The Governance of Genomic Research: The Case Studies of Iceland and Newfoundland and Labrador

by © Bora Salman

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Abstract

Genomic research and databases came into prominence following the large-scale scientific research and investments into human genetics in the 1990s. Genome-based knowledge, which promises new diagnostic and therapeutic techniques, also produces political, economic, ethical, social, and regulatory dilemmas. The thesis examines the governmental, techno-scientific, and economic power-relations lodged in genomic research. The thesis focuses on Iceland and Newfoundland and Labrador as the cases, which attracted venture capital investments and research because genetically homogenous populations are ideal for conducting genetic research to detect the roots of the diseases. With a Foucauldian lens, the power relations between the subjects including, biotechnology and pharmaceutical companies, venture capitalists, patients' groups, and state, are analyzed in parallel with neoliberal governance model. Biotechnology companies*,* investors, and governments play significant roles for supporting the biotech industry. Discourses of rational self-interest and personal responsibility are deployed, in particular cases national identity and ethnic pride are also articulated with the emphasis on the rational self. These discourses mask not only ethical concerns, but also power relations between the parties. The comparison of the governance alternatives in these two cases tries to offer insights regarding neoliberal governance model, which mobilizes individual conduct in line with political economic ends.

Keywords : Biotechnology, genomics, genomic research, governance, Foucault

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CHAPTER ONE- INTRODUCTION

1.1) Overview

This thesis project will explore genomic research and the associated governance mechanisms with a focus on knowledge and expertise in the life sciences. The governance mechanisms emerged in the context of the neoliberal political economy and affected the field of genomics, a bourgeoning section of the biotechnology industry. The governance realm is informed by techno-scientific developments and political and economic factors, and as the thesis argues, which results in alternative governmentalities. The thesis analyzes the governmental, techno-scientific, and economic power-relations lodged in genomic research and new medicine grounded in genome-based knowledge. In this research, the act of governance will not be limited to the state as a single actor. Using a Foucauldian lens, the thesis examines the complex webs of power relations between the subjects including, biotechnology and pharmaceutical companies, venture capitalists, and patients' groups, as well as state agency. This multifactorial trajectory helps to illuminate the emergence and functioning of genomics within the neoliberal model. It also assists in covering issues, such as the genetic reductionism, the commodification of health knowledge, and the formation of the new group and individual identities situated between health and illness.

Personalized or precision medicine is a new approach that promises to re-engineer and transform life with early interventions and treatments designed according to the genetic characteristics of individuals. Personalized medicine is a set of "treatments targeted to the needs of individual patients on the basis of genetic, biomarker, phenotypic, or psychosocial characteristics that distinguish a given patient from other patients with similar clinical presentations" (Jameson & Longo, 2015, p.

2229). In this sense, individually tailored medicine, which relies on genetic research to detect the individual differences of patients at the molecular level, might help improve the efficiency of medicine to cope with numerous diseases. However, scientific discoveries facilitate the manipulation and transfer of human genetic material (Rose, 2007). Genome-based knowledge, this thesis shows, produces political, economic, ethical, social, and regulatory issues.

Genomics and personalized medicine have been subjects of debates to improve healthcare outcomes. For instance, Ricciardi and Boccia (2017, p. 36) claim that personalized medicine is a path for sustainable healthcare, which requires a radical shift in medicine towards disease prevention and early diagnosis and relies on a more participatory model of empowered citizens. The promissory discoveries in genomics and the application delay in health care practices increased the calls for actions on the governance mechanisms that facilitate this field. According to Khoury et al. (2011, p. 487), a broad-based approach to human genomics through multilevel interventions, including policy change, clinical–public health partnerships, and consumer and provider education, should be deployed for the gap between the scientific discoveries and healthcare outcomes. Knoppers et al. (2010, p. 225) support the access of governments and researchers to genomic databases, as well as the construction of those biobanks with public funding to integrate genetic knowledge into healthcare effectively.

This thesis focuses on Iceland and Newfoundland and Labrador (NL) because their alternative governance models bring light to political, economic, ethical, social, and regulatory controversies. Even if these governance models are inconsistent and not entirely effective, they provide researchers with valuable sources to analyze policy-making processes and the articulation of different discourses with research projects, such as national norms in Iceland and redistributive justice in NL. The entrepreneurial model and provincial approval model developed in Iceland and NL respectively have influenced additional attempts to construct genetic databases throughout the world, in particular in the UK.

The biobank projects, both in these cases and in other parts of the world, are contemporary strategies of biopolitics to govern life. As Gottweis (2008, p. 25) points out, ”body surveillance in the context of the developments of contemporary life sciences means something distinctly different than in earlier time, with respect to surveillance, with respect to bodies, and with respect to the shaping of the infrastructure of surveillance and monitoring- the shaping of the structure and the organization of institutions of monitoring bodies and population.” In this sense, the case study analysis of this research explains how biotechnology companies, venture capital investors, and governments support the biotech industry, including biobanks. I argue that biotech supporters deploy the discourses of rational self-interest, personal responsibility, and self-care. In addition, national identity and ethnic pride are also articulated with the emphasis on the rational self. These discourses mask not only ethical concerns, most notably the potential violation of patient privacy, the impossibility of obtaining meaningful consent given the inherently communal nature of genes, and genetic determinist trend in medicine with respect to the roots of illness, but also power relations between the parties involved.

The comparison of the cases will offer crucial insights into the functioning of the neoliberal governance model. The neoliberal governance model mobilizes individual conduct in line with political-economic ends. This model also aims to manage the tensions associated with private enterprises and national values. Within the context of the cases in this thesis, the hybrid mechanisms of public and private partnerships and the articulation of nationalistic discourses with the global economic targets through the neoliberal governance model are analyzed. Through the articulation of local and global dimensions under neoliberal governance, the mobilization of individuals towards a specific reference point is realized.

An appropriate policy response, amid the different conceptions and debates on genomic research, is crucial for the future of healthcare. In this sense, this thesis will examine the governance mechanisms for the regulation of genomic research, the translation of knowledge, which is generated through these scientific activities, and the adaption of precision medicine into health practices. In so doing, the governance mechanisms in the cases examined and the capacity of the governance alternatives to address political, economic, ethical, social, and regulatory issues will be discussed in this thesis.

1.2) Literature Review

Genome-based knowledge and technologies produce complex governance mechanisms and have health policy implications that have yet to be fully explored by the literature in social sciences. The shifts in medical knowledge, healthcare, and regulatory framework as a result of genomics and genetic databases represent a radical transformation that requires a comprehensive perspective. However, the literature on genomics concentrates on particular subjects and processes with a limited scope, therefore resulting in a gap in the literature. The ethical debates on the informed consent mechanism, the governmentality analysis of genomics with a focus on molecularization of life and politics (Rose, 2007), and the microphysics of power relations, and the new concepts of the social studies of science and technology (STS) scholars about the subjectification and knowledge production processes bear these limitations in their theoretical perspectives.

The scholarship on ethical issues is constructed on the principle of individual autonomy in parallel with the neoliberal economic model. The debates of “the right to know versus the right not to know” (Chadwick et al. 1997) and “rights and responsibilities in the face of genetic knowledge” (Rhodes, 2002) can be exemplified as the focus on the autonomous rational subject excluding the subjectification and power relations (Bunton & Petersen, 2005, p. 13). Indeed, Chadwick et al. (1997, pp. 19-20) claim that autonomous individuals can reasonably decide on genetic testing on the grounds of the right to know if they are genetically susceptible to specific conditions according to whole-genome sequencing or other predictive measurements. Rhodes (2002, p. 420) has a similar position about individual autonomy when she questions the responsibilities of individuals to each other regarding genetic knowledge. The informed consent mechanism with an emphasis on autonomous subjects is affirmed as a primary instrument regarding the research participation as well. For instance, McGuire and Beskow (2010, p. 376) suggest a model of consent that relies on communication with research participants to honor participants’ altruism and respect their autonomy. Knoppers and Chadwick (2005) discuss the emerging trends in the ethics of human genetics research, such as reciprocity, mutuality, solidarity, citizenry, and universality, marking a communitarian influence on ethics, as well as distributive justice debates. The ethical debates can exclude the subjectification processes, in a Foucauldian sense, the process through which human beings become subjects, and microphysics of power relations, portraying individuals as autonomous rational subjects.

The incorporation of governmentality analysis into genomic research and associated problems produced better analyses that did not ignore the subjectification processes. For instance, Rose (1993) illustrates how new strategies and techniques administer individuals in an uncoercive way, paving the path for the analysis of power relations beyond the realm of state and oppression. Miller and Rose (1993), using Bruno Latour's notion of action at a distance, illustrate how political authorities combine personal conduct with socio-political objectives. For example, economic growth is governed via experts and expert knowledge. Neoliberal governmentality comprises of indirect mechanisms and techniques which entangles the personal conduct of individuals with political-economic targets; at the same time, individuals are convinced that their conduct is aligned with their own self-interest. These narratives filled the gap in ethical debates that presuppose individuals as autonomous subjects. The inclusion of the actors to make a governmentality analysis beyond the state mechanism undoubtedly provides better insight. However, as Jessop (2011) criticizes, Anglo-Foucauldian école, such as Burchell, Gordon, and Miller (1991), Miller and Rose (2008), exclude the function of state mechanism while managing the inclusion of the micro-physics of power into the analysis.

The state undertakes a central role under the neoliberal model. This role is not in parallel with an understanding of the state as an entity outside of social and economic production. However, instead of state mechanisms and the normative choice between the public and private initiatives, the alternative objects of analyses are also developed in a Foucauldian vein. For instance, Valverde (2016, pp. 212-13) focuses on the governance networks beyond the binary public and private distinction and claims that the *ad hoc* hybrid governance mechanisms are not a mere result of neoliberalism that existed before it. The power is not fixed and not limited to the political domain. However, her "post-institutional perspective" provides minimal insight into the shift in the rationality of political power as a result of neoliberalism and the construction of the hybrid mechanisms that she defines as assemblages. Actually, "what we observe today is not a reduction of state sovereignty and planning capacities but a displacement from formal to informal techniques of government and the appearance of new actors on the scene of government "(Lemke, 2007, p. 57). As such, an analysis of genomics that takes non-state actors into consideration will help better apprehension of the phenomena. However, the state mechanism that undertakes new and crucial functions under neoliberalism should not be ignored in order to render a theoretical perspective insightful as far as possible.

Among STS scholars, there is an interest in genomics as well. These scholars attempted to define developments in this field with new terminology and narratives, mostly with new concepts as well. In some cases, these efforts to explain the transformation of knowledge production in life sciences created the vagueness about the content of the concepts. For instance, Rajan (2006) combines a Marxist account of economic terms with the Foucauldian narrative of biopolitics to develop the biocapital terminology. Rajan (2006, p. 4). traces "a mutual constitution of the scientific and the social as a coproduction" while investigating the development of novel biological sciences in cooperation with political regimes. This research offers some helpful insights, such as the connection between the subjectification and value. However, his arguments lack the basis to define biocapital as a new mode of capitalist accumulation, even if this new mode is defined as an alteration, not a radical rupture. A rigorous account of these new bio-concepts, such as biovalue, biolabour, bioeconomics, biocapital, biocommodification, is illustrated by Birch (2017). He criticizes this enthusiasm of the scholars of STS to theorize modern biotechnology, life sciences, and bioeconomy in a sense which engenders the "fetishization of everything bio-," thus complicating the analysis of the relation between the modern life sciences and (bio)economy (Birch, 2017, p. 916). The abundance of these concepts with bio- prefix among STS scholars is likely to create ambiguity inasmuch as the fashion for coining new concepts clouds the meaning that they contain. Birch argues, scholars overapply Foucauldian biopolitics terminology to analyses of bioscience.

There are also publications in social sciences on the social implications of new technologies in genetics and medicine. Indeed, precision medicine based on genomic knowledge, techno-scientific developments, in general, are not value-neutral innovations, achievements, or discoveries external to the social body. These arguments are supported well within coproduction and socially informed technology narratives. Scientific knowledge is a co-production embedded by social discourse and contexts (Jasanoff, 2004). Within this context, “specifically desired ends are built into the knowledge and techniques of biomedicine, bioscience, and biotechnology, in a manner in which technology is socially informed” (Franklin & Lock, 2003, pp. 4-5). Rabinow (2005) offers a new term while examining the new genetics, biosociality, as a network of identity terms beyond a biological metaphor. “If sociology is culture constructed on the basis of a metaphor of nature, in this new form, nature will be modeled on culture understood as practice. Nature will be known and remade through technique and will be finally become artificial, just as culture becomes neutral” (Rabinow, 2005, pp. 186). Biosociality represents the formation of the new group and individual identities situated between health and illness, such as carriers of genetic susceptibilities. The concept of biosociality also explains how new groups and identities are formed around new concepts of diseases. However, beyond the analysis of micro-power, anatomo-politics at the molecular level, and the biopolitics concentrating on the molecular level (Rose, 2007), the factors at the macro level that impact the global mass of individual bodies should also be taken into consideration for a robust analysis as this research adopted.

Genomics is a set of techno-scientific practices; it also functions socially and culturally to interpret and transform human bodies. The extension of medical interventions into life, which becomes a major institution of social control and a new repository of truth, had been previously discussed (Zola, 1972), before the era of genomic discoveries. Biotechnological developments have been, however, technical means to facilitate both further diffusions of medicine into everyday life practices and redefining the normal through new preventive approach in the healthcare that focused on individual genomes. Clarke et al. (2003, p. 163) claim that “medicine as a politico-economic institution and sociocultural good grew” which transforms knowledge production and human bodies co-producing technoscience and social forms together. The literature regarding how medicine plays a role in shaping perceptions about life is a limited scope as compared to the Foucauldian lens, which offers a more complicated portrait of the role of medicine (Lupton, 1997). However, critiques on the capacity of new genetics to create alternative discourses can be combined with the Foucauldian governmentality perspective to illustrate how these discourses mask coercion.

In Foucauldian terminology, the analysis of micro-power is not limiting in terms of scale to exclude a macro analysis; it is a point of view, a methodological approach (Foucault et al., 2008, p. 186). The factors, such as the global dominance of neoliberalism, articulation of political-economic grounds, constitute the conditions through which the biotechnology industry and techno-scientific developments in medicine emerge. Therefore, these factors at the macro level and transformation of state under the neoliberal model as a vital factor of the facilitator of new economic activities should be included in the analysis of emerging sectors of the knowledge economy, including genomics. As Jessop indicates (2011, pp. 60-61), Foucault explored not only the generalization of the conduct of conduct across diverse spheres of society but also studied how specific governmental practices and regimes were articulated into broader economic and political projects.

In sum, there is a gap within the literature on the analyses of genome-based knowledge and governance of genomics. The ethical debates associated with genomic research are constrained with the informed consent mechanism, which relies on rational subjects, individual autonomy, and empowerment discourses. The attempts to integrate governmentality to the analysis of genomics successfully illustrate the microphysics of power relations, whereas the emphasis on the “political power beyond state“ (Rose & Miller, 2010), which underestimates the role of state mechanisms, limits the depth of the analyses. The extension of medical and genetic concepts into daily life practices, defined as medicalization (Zola, 1972), biomedicalization (Clarke et al., 2003), the formation of new identities called biosociality (Rabinow, 1992), and the co-production of scientific knowledge (Jasanoff, 2004) provide insights abut the subjectification processes. However, these theoretical approaches are not sufficient to cover the transformations as a result of genome-based knowledge through which the biological existence is reconceptualized in social and political-economic contexts.

1.3) Theoretical perspective

In this thesis, a theoretical perspective that aims to integrate the micro and macro level of analyses is deployed. In this sense, the theoretical perspective encompasses the microphysics of power relations and the actors involved in genome-based knowledge production, and macro-level political relations to include state agent. By combining these levels, this thesis examines on a theoretical basis the capacity and techniques of the governance mechanisms to produce discourses that mobilize individual conduct and articulate them with macro-economic targets.

A Foucauldian perspective is appealing to analyze the techno-scientific developments of the age of the genomics and power relations between the subjects because it provides a more robust analysis of the techniques for control over the biological existence of individual bodies and population, at micro and macro levels, and subjectification processes for governable bodies. From this point of view, the human body is not outside medical discourse and practices. On the contrary, “the biological existence of the human subjects, body and its various parts are constructed through discourses and practices, through the clinical gaze exerted by medical practitioners” (Lupton, 1997, p. 195).

Dynamics of power are complex and associated with several interwoven and contextual factors, contrary to the premises of the classical model of sovereignty in which power and knowledge are external to each other, by reducing power to domination and repression, which is not able to reflect the multiplicity of power relations (Foucault, 2003). Foucault offers an alternative theory for the genealogy of relations of power than the classical theory of sovereignty. In fact, power always relies not upon coercion, but discourses in which individuals feel that they pursue satisfactions, such as happiness and wellness. Truth and power are not external to each other; modern power is able to mask itself by producing alternative discourses (Dreyfus & Rabinow, 1983). Turner (1997) states medicine is accepted as legitimate in everyday life through this capability of masking despite its disciplining function. Foucauldian analysis has a great competency to reveal the discourses that mask the coercive features embedded in the empowered subject of neoliberalism and new genetics promising novel solutions in medicine. The numerous and diverse techniques used to intensify genomics and precision medicine serve for the subjugation of bodies and the control of populations in a biopolitical sense (Foucault, 1978, p. 140).

Foucault’s biopolitics is a pivotal term for this analysis. This notion explains how technologies of power function to control life through its two poles, the control of the body, labeled ‘anatomo-politics,’ and the control of the species, labeled ‘biopolitics,’ operating at the level of the population. “The disciplinary techniques targets individuals to create docile bodies under surveillance through institutions like schools, hospitals, and armies, whereas regulatory techniques aim at populations as a global mass of individual bodies” (Foucault, 2003, p. 241). In close relation with biopolitics is governmentality. The meaning of governmentality or the term of government in a Foucauldian sense range from governing the self to governing others, “the conduct of conducts” that is to say, a form of activity aiming to shape, guide, or affect the conduct of some person or persons, the government of one’s self and of others” (Gordon, 1991, p. 2). Foucault links governmentality, which is a novel art of government composed of new tactics and techniques, to the notion of biopolitics. Governmentality is “the ensemble formed by the institutions, procedures, analyses, reflections, the calculations, and tactics that allow the exercise of this complex of power, which has as its targets population, as its principal form of knowledge political economy, and its essential technical means apparatuses of security “(Foucault, 1991, p. 102). Biopolitics and governmentality together offer critical insight into expert knowledge and scientific discourse around the genetic knowledge and techniques, as well as the governance of this space under the rationalities of neoliberal governmentality.

Personalized medicine and neoliberal policies on health care center ‘patient empowerment,’ and as such, it is a pivotal term. According to this notion, patients as unconstrained subjects are supposed to become informed participants in research projects, administrators, and coordinators of their health data. This patient typology represents a radical shift in the role of patients compared with the traditional role assigned in healthcare. Patient empowerment is not consistent with the technologies of the self for bodily optimization. For Foucault (1988, p.17), these technologies are “practices to transform one’s own body and mind to affect their own bodies and souls, thoughts, conduct, for transforming the self to attain happiness, purity, wisdom, perfection, or immortality.” The empowered patients seem to resemble the actors in the search for self-maximizing as per rational principles in the market rather than those practicing technologies of the self. Patients, who are free and active subjects towards their personal enhancements as consumers of diagnosis and therapeutic products of pharmaceutical and biotechnological industries, are the theoretical foundation at the molecular level for the development of medicine based on genotypes.

Discourses, including patient empowerment, that mask power relations are the crucial factors to the conduct of individual conduct in that power does not rely on oppression and coercion. “Power is not so much a matter of imposing constraints upon citizens as of making up citizens capable of bearing a kind of regulated freedom“ (Rose & Miller, 2010, p. 272). In this sense, individuals do not feel themselves oppressed while making decisions on their wellness as empowered subjects. However, neoliberal governmentality guides them to live the freedom in which individuals discipline and regulate themselves through the rights and responsibilities of being rational subjects. The “conduct of conduct” explains the manipulation of uncoerced subjects in parallel with the targets at the macro level.

In this sense, empowerment rhetoric turns into a novel form of domination and a bipolar subjectification, causing both enhancement and subjugation. Precision medicine, aiming to substitute a one-size-fits-all approach, is constructed on the ideal of the informed consent to ensure individual autonomy. However, this idealistic discourse produces individuals as autonomous and rational subjects and gives the responsibility of healthcare choices to patients. Reardon (2012, p. 27) points out that "twenty-first-century efforts to map and characterize human differences at the genomic level present us with a different problem of power and science. This problem derives not from domination, but freedom." Therefore, exclusion based on genetic determinist approach to the roots of diseases and disempowerment emerges as a product of practices that are said to free individuals.

The patient empowerment discourse also ignores health literacy levels, differences in the economic resources of patients, and their motivation for participating in medical procedures. As Cooper and Waldby (2014) illustrate, poverty is a fundamental reason for research participation or donation of biological material for those with no alternative access for medical treatment. The way in which public health responsibilities are transferred to at-risk individuals by reducing personal differences to merely genetic profile might exacerbate healthcare injustices. Additionally, it is highly likely that empowered subjects faced with highly sophisticated diagnostics and therapies of personalized medicine may not have the ability or expertise to guide their care effectively.

The neoliberal governance model reconfigured the distinction between the public and private spheres because of the special position given to the market in social organization. Public services are pressured to be more effective and innovative, leading to public-private sector collaborations and hybrid governance models. As a result, the introduction of market-based solutions in the public sector, especially in healthcare, which is not a just a technical issue; on the contrary, a political decision to redistribute healthcare responsibilities, changes the concept of healthcare from a population-based approach to optimized care in entrepreneurial terms (Scheil-Adlung, 1998, pp. 134-135).

This model shapes state mechanisms towards a competitive global economy and innovative industries like biotechnology and the ‘competitive state’ (Cerny, 1997). The shift in the function of the state mechanism is highly significant because the states became agents in the fostering of emerging biotechnology sectors for competition purposes. Competitiveness through knowledge-based economies motivated states to support the biotechnology sector. Through public funding and flexible regulatory regimes, states supported innovative sectors to increase their competitiveness in the global economy, as well as the collaborative enterprises with private sector agents. Shorett et al. (2003) suggest that developments in biotechnology is an example of the successful collaboration of the scientific discovery of the universities and public research facilities and product development of the private sector under favorable regulatory regimes, most notably University and Small Business Patent Procedures Act of 1980 in the USA, known as Bayh Dole Act, creating an active role for citizens as investors and consumers. According to the Act, scientific discoveries resulting from publicly-funded research can be patented, which represents a milestone for academy-industry partnerships. In this sense, states maintain global competitiveness through the funding of research and development activities through academy-industry collaborations, which are supported by advantageous regulatory regimes to protect the property rights and patents. “Particularly in the case of the knowledge-driven bio-industries, this meant a concentration not only on the infrastructures of innovation but also on ‘agglomeration and network economies and the mobilization of social as well as economic sources of flexibility and entrepreneurialism“ (Salter & Faulkner, 2011, p. 2). The establishment of national biobanks, which are genetic databases using the principle of genetic homogeneity, are also examples of biopolitical projects in consistent with these economic incentives. As Gottweis (2008, p. 29) points out, “at the same time, biobanks have also been conceptualized as a mechanism to promote international competitiveness."

The neoliberal governance model functions on the basis of the market, which functions according to the competition principle rather than the principle of regulation. The notion of *homo oeconomicus* or economic man is a central figure in this setting, extending beyond the economic domain to involve all aspects of social life in the neoliberal model (Foucault et al., 2008, p. 268). In this sense, neoliberal governmentality shapes the personal conduct of individuals on the basis of rational choices of empowered subjects in the privatized and marketized health services. Larsen and Stone (2015, pp. 946-47) point out that manipulating economic incentives becomes a vehicle for directing individual behavior, whether the behavior entails a patient's demand for certain health services or a doctor's decision to prescribe certain treatment. In the entrepreneurial society, individuals are supposed to invest in their health as consumers of the products of new medicine based on their genetic dispositions, therefore investing in themselves.

The hybridization of policies is also another feature that develops together with the neoliberal model. Based on the blurring of the distinction between public and private, hybrid mechanisms result not only in the extension of the "privatized" state enterprises into other domains but also new forms of sovereignty (Hibou, 2004, pp. 3-4). The hybridization can be in the way of utilizing the benefits of economic activities, which blossomed with neoliberal policies for redistribution and social policies (Torrado, 2016, p. 699). In this way, national states and private enterprises that invest in new economic sectors are major actors to maintain popular support for the governments and economic activities. Transnational agencies can also function in the hybridization scheme by endorsing policies that generate positive social impacts as well as economic ones. For instance, Dean (1995) analyses the policy change in the income support for unemployed people replacing the unemployment benefit scheme with a differentiated structure of benefits tailored to fit the particular requirements, which is supported by the Organisation for Economic Co-operation and Development (OECD) within the context of active society as well. He observes the hybrid nature of the policy aiming at various politico-administrative goals and ideals, such as income redistribution, alleviation of poverty and disadvantage, equity, efficiency, and social justice. These goals involve practices of self-formation, practices concerned to shape the attributes, capacities, orientations, and moral conduct of individuals as governmental-ethical practices (Dean, 1995, pp. 567-68). In these initiatives, the targets of social policies are subdued by the ends to regulate individual conduct towards a particular understanding, such as an active society. In this sense, the hybridization stands for the extension of the state function through policies conducted with private sector partnerships, as well as the growing capacity of the opinion-making of this new political-economic setting.

The techno-scientific developments in biomedicine and precision medicine are historical consequences of the political-economic factors accelerating the need for the policy alternatives in the health services and promotion. Globalization, the crisis of welfare state, and global hegemony of the neoliberal economic model and the discourses associated with have affected public health policy and services. Neoliberalism, in brief, produces discourses that affect the emergence of genomics as a sector and the alternatives of governance at two levels. The first one, at the micro-level, is the patient empowerment discourse in which empowered individuals search for self-maximization in goods and services, including customized public services. Through this discourse, individual conduct is manipulated to comply with targets at the macroeconomic level. The second one, at the macro level, is the competition state discourse in which states play a central role in supporting economic development through hybrid governance mechanisms in collaboration with the private sector. As a result, public services are reconfigured to maximize output with market principles and an entrepreneurship mentality through new techniques and strategies, including the calculation of service costs, outsourcing, or service level changes policies.

A transition to new understanding in medicine and health care delivery, as well as the application of new technologies into health practices, became compulsory as a result of the global hegemony of the neoliberal economic model. There was a trend in health policy side, which Gottweis et al., 2009 defined as “global techno-managerial paradigm,” focusing on free-market solutions, efficacy, and techno-scientific innovations and its application to health practices. The publicly-funded health care systems became an extension of the market as technical means for healthcare provisions. As Tutton (2016, p. 10) exemplifies, “initiatives such as British Government’s introduction of personal health budgets for people with chronic illness with the aim of enabling them to customize their own health management” delineates how publicly-funded healthcare systems transform under neoliberal policies. In parallel with new market-based principles, public services, including health care, became key areas for the assimilation of techno-scientific innovation into society.

Political-economic transformations resulted in the societal impacts and changes in knowledge production as well. The significant epistemological shift in medicine and the medical gaze emerged as a result of techno-scientific developments in genomics. In the nineteenth century, life and corporal existences were conceptualized with normal or pathological categories. In a similar vein, the biotechnological developments reconfigured medicine and medical knowledge and replaced the monopoly of medical doctor’s expertise on diagnostic gaze. Through this transformation, the diagnostic practices of clinicians have been accompanied and partially substituted by novel diagnostic techniques, bioinformatic systems used for making statistical predictions, and correlations between the patients through genome-based knowledge and genealogical information. In this transformation, new value creation processes also emerged. “Biovalue refers to the yield of vitality produced by the biotechnical reformulation of living processes” (Waldby, 202, p. 310). Rose (2007, p. 11) points out, this is the “the molecularization of styles of biomedical thought, judgement and intervention” which resulted in the new techniques of medical interventions and the economic exploitation of human vitality. This, therefore, creates new fields for the expertise in which genome-based diagnostic tools transform the human body into a commodity to be exploited economically. The technical means to render human tissues transferable at the molecular level contributed to this exploitation. However, the political-economic factors, the neoliberal shift in public services towards privatization, and the state policies to support high technology sectors under the competitive global economy provided the necessary settings to construct an economic domain from techno-scientific discoveries.

The governance alternatives for genomics stand at the nexus of the hybridization of policies: the neoliberal policies and the social policies to incorporate the research outcomes into healthcare, as well as sharing the benefits as a result of population-based research among the community. On the one hand, the idea of the reconstruction of public services, including healthcare, and society at all, by reference to the market, for-profit investments into genomic research, and mobilization of personal conduct as per rational choices motto prevails. On the other hand, an understanding of public health research and population genomics databases as being public goods (Knoppers et al., 2010, p. 230), in order to maintain science-state concordat to maximize the delivery of economic, health, and social benefits, as well as the advancement of scientific power (Salter & Salter, 2017, p. 270). How do these ends diffuse into governance alternatives for genomics? Are the market-driven and for-public benefit understandings able to coexist in the governance mechanisms? Under the hybridizing effect of the neoliberal policies and their ability to mask the discourses serving for subjectification, it is possible to say that trade-offs between the policy alternatives are realized within the boundaries of the neoliberal model and discourses associated with. In this sense, the governance alternatives of genomic research diversify to the extent that state and transnational agencies apply economic and political strategies to biotechnological innovations.

In brief, as an emergent field within the biotechnology sector, genomics followed the path created by the neoliberal economic model. This field was fostered by the states in parallel with their new functions under neoliberalism and the growth model that relies on knowledge-based economies. In the governance of genomics, the hybrid policies that came to prominence with neoliberalism play a central role. This hybridization has two interconnected dimensions. The first one is the partnership between the public and private as a result of new functions of state. The second one is related to the content of policies, which, on the other hand, aim to realize economic targets; on the other hand, shape individual conduct through discourses in parallel with macro-level ends. The governmentality approach provides an in-depth analysis of the changing political rationality, strategy, and techniques, as well as subjectification processes. Through this approach, it is possible to examine the governance mechanisms regarding genomics and policy trade-offs.

1.4) Methodology and Data Collection

The method of the thesis is case-study based. This method provides an in-depth understanding of phenomena, their constitutive process, and the actors involved, which can be used to build and validate a theory (Gagnon, 2010, p. 2). The case study method also has some limitations. It only permits the understanding of a single facet that is intrinsic to the case under investigation but studying others, such as the comparison between cases, helps moderate this constraint (Hamel et al., 1993, p. 35). In this vein, this research focuses on Iceland and the Canadian province of Newfoundland and Labrador (NL) as the cases to examine in-depth the genomic research projects and governance methods associated with them. In order to deal with the limitations of studying peculiar cases and making a microanalysis, an analysis of the biotechnology sector on a global scale will also be conducted in this thesis.

The data used in the thesis relies on three different kinds of sources. The first one is a literature review concerning the emergence of the biotechnology sector, neoliberal governmentality, and the endeavors in genomics in Iceland and NL. The second one is an analysis of policy documents regulating the genomic research activities and health policies for both cases, as well as publications by transnational organizations on genomic research and precision medicine. The last source is fieldwork conducted in Iceland from September to October 2019 to examine the Icelandic genome project and the Health Sector Database Act, and more specifically, Icelandic genome-based research and knowledge, and the transformation into health practices.

This fieldwork consists of two pillars. The first one is an archival study in the National Library of Iceland, in particular, the Timarit database, newspapers, and periodicals of the Faroe Islands, Greenland, and Iceland. The second one is interviews with Vigdis Stefansdottir, a Genetic Counsellor at Landspitali University Hospital, as well as another Icelandic scholar. In these interviews, the application of the knowledge generated through the Icelandic genome project and the issues associated with this research project, such as privacy concerns, consent mechanisms, and the affordability of new discoveries, were questioned.

1.5) Case Studies

The analysis of this thesis dates back to the last decade of the twentieth century when large-scale projects to determine the genetic roots of diseases were launched. The most prominent initiative was the Human Genome Project, which was operated by a broad-spectrum consortium consisting of government offices and scientific community and was dependant on pharmaceutical companies for funding. The temporal complexity of studying how genome-based knowledge diffuses into society is crucial. This complication is not only because the accurate process-tracing on genomics can easily turn back to the period what Gottweis (1998, p. 39) “trace the politics of molecular biology to its origins in the 1930s”. In his trajectory, he also focuses on the 1950s and 1960s when states started to become involved in governing molecules actively through policies, strategies, and institutions. (). It is also a consequence of how the way of writing the history of genomics needs an insight into the subject that Fortun (2001a) describes as a ‘future anterior.’ This perspective that can be summarized with an idiom of “what will have been” represents the promissory feature of genomics and its forward-looking statements (Fortun, 2008). As Helmreich (2008, p. 468) indicates, “Mike Fortun suggests that understanding the business of genomics requires attention to its speculative logic, which he examines by demonstrating the role of ‘forward-looking statements’ in generating investment and profit”.2008, p. 468). “Genomics companies, like deCODE Genetics, Celera, Millennium, and Human Genome Sciences have existed entirely in a historically specific regulatory framework of corporate disclosure- a framework that sanctions and encourages the promissory quality of the forward-looking information which these corporations produce and thrive on" (Fortun, 2012, p. 340).

Iceland has been at the center of a global debate on genome-based knowledge, and NL has a similar position. Both locations are unique because of their relative isolation and therefore have great potential for studying the genomic roots of complicated disorders (Gibbs, 1998, p. 34; Zhai et al., 2016, p. 1063; Rahman et al., 2003, p. 167). As a result, global venture-capital has targeted both sites and has developed local genome-based research to conduct clinical trials for drug development.

In particular, the case of Iceland's deCODE Genetics has become known worldwide, and its CEO, Kári Stefánsson, turned into an icon of the new genomics industry (Gottweis & Petersen, 2008, p. 5). Founded in the USA by Stefansson, a neuroscientist at Harvard University, and Jeff Gulcher, deCODE is funded by venture capital funds that were willing to invest in the Icelandic gene pool before the start of the company's operations in Iceland. During the preparation phase, deCODE was able to make a deal with pharmaceutical giant Hoffman-LaRoche valued at $200 million in exchange of collaborative research on Icelandic genetic properties with the aim of drug development, which gave the company huge credibility in Iceland, attracting foreign investment to country (Árnason & Wells, 2003). deCODE's public relations used nationalist pride rhetoric to show that their contributions were unique and would make a revolution in medicine. Árnason and Wells (2003) point out, project's economic gains were expansive according to the company, for example, the employment of skilled workers, the reversal of the brain drain, contributions to the Icelandic economy, a catalyst for a biotechnology industry, as well as support for research and healthcare and the promise of free drugs. As a result, the company was given a license in return for a fee to construct the database called as Health Sector Database (HSD) on the basis of presumed consents of participants, which means research subjects were presumed to give their consents unless they opted out. Pálsson (2008, p. 44) states, "a legal and ethical model or framework for such a comprehensive, national project was nonexistent before HSD, which was a pioneering enterprise."

The Icelandic Genome Project consists of three different elements: healthcare data based on medical documents since 1915, genetic information obtained with sample collections, and finally, genealogical records dating back to the ninth century based on Icelandic sagas, church, and state records. Three different databases, "medical, genetic, and genealogical, formed a comprehensive Biogenetic Project" (Pálsson & Hardardóttir, 2002, p. 272). deCODE contracted an Icelandic software company to create a database called Book of Icelanders, which compiled the records from the ninth century and made family connections with the records. This database contains "approximately 700.000 records, the majority of people born in Iceland since the first Norse settlement in the ninth century "(Pálsson, 2007, p. 70). It is possible to combine the genotypic data, which was collected by participants on the basis of informed consent through blood samples, with medical information available in HSD. The comprehensive database is supported by arguments on efficiency and national norms. According to Stefansson and Gulcher (2000), the medical records were already accessible to medical service providers, and provisions of HSD on the encryption of medical data will establish a more effective system for the protection of privacy. Pálsson (2007) also supports this argument exemplifying the Blood Bank and the Cancer Registry databases, which record biomedical information of patients dating back to the 1950s. Pálsson (2007, p. 97) also adds that family histories were already available in public, and the project was able to gain public support because it addressed the passion of Icelanders for keeping genealogical records. The rhetoric of setting a database, which will protect the gene pool of the country as a national value in a way respecting national norms, serves as a tool to mask the neoliberal incentives of the project.

The Iceland project is valuable because of the controversies that arose during its implementation. Issues of privacy and consent were raised as the project progressed because of opposition to the project. The Association of Icelanders for Ethics in Science and Medicine was established by clinicians and academicians in reaction to the project. They stated their opinions in media and public debates. During these debates, a gap between the Icelandic society and deCODE Genetics became suspect, and a critical public had developed, which caused substantial damage to the project. The decision of the Icelandic Supreme Court supported the privacy concerns in the practice of database, which caused to stop the activities from setting HSD in 2003. Even if deCODE Genetics continues its operations, the mistrust of the public to the project and the global financial crisis contributed to the bankruptcy of the company.

The company was purchased by Amgen, a US biotechnology giant, in 2012 and is now operated as a wholly-owned Amgen subsidiary. Currently, deCODE launched a website whereby Icelandic people can check if they carry BRCA gene mutations responsible for breast and ovarian cancer using their national ID numbers. After its proposal to contact each carrier of those gene mutations was not approved, deCODE publicized information on a website. According to an article in the Reykjavik Grapevine by Demurtas (2018), Kári Stefánsson states that the carriers of BRCA gene mutations are most likely to, with a likelihood of 86%, get breast or ovarian cancers. The company advised women to apply for genetic counseling even if they were free of any complaints. deCODE has been subject to debates during the efforts to establish HSD and continue to do so after because Stefansson opposed the denial of the company's offer to inform mutated BRCA carriers personally.

The Icelandic genome project is highly influential in the debates about genomics and endeavors for other databases because the Icelandic case has several unique features. It is the first and most contentious database initiative. The Health Sector Database is the first act in the world regulating the genomics field as well. The controversial points are basically caused by the consent mechanism according to which the project operated. For Kaye (2004, p. 117), " the main objection to the Icelandic population collection was that informed consent the internationally agreed standard for biomedical research was not sought." The presumed consent mechanism and controversies associated with, such as privacy and the protection of individually identifiable data, were discussed at national and global levels. In this sense, "inspired by the Icelandic project, but also learning from the controversies that surrounded it, two further proposals for large genetic databases followed in Britain and Estonia" " (Corrigan & Tutton, 2004, p. 4).

The story of genomic research in NL begins with researchers from the Baylor College of Medicine in Texas who came to Grand Falls in 1998 and collected DNA samples from the local people and family histories within the context of their research on Arrhythmogenic Right Ventricular Dysplasia (ARVD) which is a heart muscle disease known as Newfoundland curse between the local people causing sudden heart attacks. This research was not well received, and the researchers were called Texas Vampires by locals. According to the article on CBC News, the family members affected by ARVD were highly ambitious about that research and volunteered for the blood samples. However, the research was not shared, and the researchers had a responsibility to do so.

The researcher’s breach of ethics prompted NL to examine human genetic research in the province. In this context, the provincial government hired Dr. Skanes to write a report in 2000. The same year, a local dermatologist Wayne Gulliver convinced Gemini, a British genomics company, which merged with US biotech firm Sequenom in 2001 to launch Newfound Genomics (Taubes, 2001). According to the *Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador Report* (2003, p. 13), Dr. Gulliver took part in a research conducted by Celltech, a California based biopharmaceutical company, regarding psoriasis in Newfoundland and Labrador. During this research, he also advocated for the storage of DNA samples collected by local people in the province after a dispute with the Celltech that denied the demand of Gulliver. The mission of Newfound Genomics was to study the genes of the island’s population using much the same approach as deCODE has popularized in Iceland. Nevertheless, Newfound Genomics did not succeed and ceased its operations because of government pressure on the company after the loans given to the company has become a source of public controversy.

During the tenure of Health and Community Services Minister Steve Kent, who was a member of the Progressive Conservatives, in 2015, the provincial government and Sequence Bio, a local company specializing in the use of genetics for the discovery of new drugs and therapies, signed an agreement for recruiting 100,000 people in the province to analyze “genomic and phenotypic” information. The agreement also had a partnership with Genospace, a company based in the USA. The officials of Genospace stated that the “Newfoundland and Labrador population is a unique resource for genetic investigation of complex diseases” (Keshavan, 2015). The literature on NL highlights its historical isolation and genomic capacity, which parallels with the experience of Iceland, which was transformed into a genetic laboratory via a public-private initiative. Sequence Bio launched Newfoundland Genome Project in 2019 with an emphasis on its contribution to the local economy after receiving the approval of the province’s Health Research Ethics Board.

1.6) Outline of the thesis

In chapter 2, the global scale content of genomics as a new techno-knowledge and new governance model will be discussed. In this context, Human Genome Project and the related issues such as public-private research distinction, academy-industry collaborations, shifts in the regulatory regime, investments of venture companies into biotechnology, and global political developments which constitute the conditions for the emergence of biomedicine will be detailed.

In chapter 3, the thesis examines the Icelandic Genome Project and the entrepreneurial model that shaped the governance of the project. This chapter is constructed on the data which was collected through fieldwork in Iceland from September 2019 to October 2019.

Chapter 4 explores genomic research activities in Newfoundland and Labrador and its governance of research. In this context, policy documents regulating genetic research, the operations of past and current genomic research companies, and the provincial ethics approval model are examined.

Chapter 5 explores the governance and policy options for balancing scientific discoveries and commercial interests in order to translate genome-based knowledge into effective public health benefits.

CHAPTER TWO- GLOBAL PERSPECTIVE

2.1) Overview

This chapter will show how biotechnology emerged as a pivotal sector in the global economy and was supported with investments in techno-scientific research activities. According to Rajan (2006, p. 5), ”biotechnology industry came about largely as a consequence of this technoscientific development in 1973 by Herbert Boyer and Stanley Cohen”. (Rajan, 2006, p. 5). However, the political-economic factors that facilitate new fields of economic activity and turn scientific discoveries into technological products are much more multifaceted than a single innovation of laboratory production. Along with scientific breakthroughs in DNA research, the 1970s also marked a turbulent period of the global economy. This decade marked an important political-economic transition characterized by the Organization of the Petroleum Exporting Countries (OPEC)oil crisis, the collapse of the Bretton Woods System, a financial fixation of global US hegemony, and critiques on the Keynesian welfare state. This transition is followed by the neoliberal revolution that came into existence, most notably through the economic policies of Thatcher and Reagan governments aiming at deregulation and privatization and international free trade in the 1980s and 1990s in the UK and the US (Helleiner, 2015, p. 88). A robust analysis of techno-scientific activity and the emergence of biotechnology as a sector requires a political economy approach because neoliberalism as a dominant political-economic model produces new economic activities and subjectification processes in parallel with the discourses.

Neoliberal policies changed the understanding of the factors of production and redesigned economic processes. In the production cycles, neoliberalism matches with a transition from Fordism to post-Fordism following economic slowdown and the decrease in the profitability of manufacturing industries in the 1970s. Unlike the Fordist production model grounded on mass production, the post-Fordist model is based on the principle of flexibility and flexible deployment of inputs in the production processes (Jessop, 1993). The composition of labor became a set of "polyvalent skilled workers and the service class" instead of the semi-skilled workers who were subsidized with the wages, including welfare adjustments in the Fordist period of mass production (Jessop, 1991, p. 144). As a result, the re-organization of the labor force in bourgeoning sectors on the basis of flexible working schemes and decrease in the number of manufacturing industries weakens the power of trade unions as a mechanism for full-employment through collective bargaining in the Keynesian period.

The post-Fordist system altered the traditional roles assigned to the household: namely breadwinner husbands and caretaker wives. The participation of women in the labor force, who were unpaid caretakers of the Fordist era, blurred the boundaries between the reproductive and productive spheres of life by integrating private space of family, including activities like biological reproduction, into the market (Cooper & Waldby, 2014, p. 5). However, gendered working conditions and wage gaps are indicators that the intrinsically coercive terms of the workplace follow the oppression of women within the family. In this sense, the subordination of women's labor resembles the disciplining function of the family. In terms of the ethos of this thesis, the genetic test targeting women to detect breast and ovarian cancers functions in a similar way to shape the everyday practices of women. Through the post-Fordist model of production, neoliberalism succeeded in the modification of the dynamics of the labor force and the industrial production and paved the way for more efficient new sectors to invest in. In so doing, strategies of neoliberal administration diminished the role of semi-skilled workers and trade unions and expectations on welfare payments. The result was a reduction in the cost of production, with a new focus on skilled workers and flexible work contracts and participation of women the labor force to expand the influence of the market into private spheres. In this sense, the extension of market into private spheres could be fully completed with the participation of women into labor force, therefore resulting in the reconfiguration of family as an institution on the basis of market logic. This transformation also represents a shift from the disciplinary to regulatory mechanisms, while the subordination of women continues.

2.2) Biotechnology as a new sector

The transformation of the state under the neoliberal model is a pivotal factor that affects the development of the biotechnology sector, including genomics. The state intervention into macroeconomics was one of the prominent features of the Keynesian model to support a nation’s targets of full-employment and welfare. However, the end of the postwar boom and the oil crisis in the 1970s increased the level of critiques on the Keynesian welfare state model revisiting classical liberal writings. The neoliberal solutions gained salience during debates on remedies for the crisis of the oversized and inefficient state mechanism as a result. Jessop (1993) argues that the theories of Austrian political economist Joseph Schumpeter are the most influential ones during the transformation of the Keynesian welfare state into what he calls as Schumpeterian workfare state. Jessop (1993, p. 9) summarizes distinctive features of this new model as: “the promotion of product, process, organizational, and market innovation; the enhancement of the structural competitiveness of open economies mainly through supply-side intervention; and the subordination of social policy to the demands of labor market flexibility and structural competitiveness.” Of these characteristics, competitiveness is a new concept that theorists of the state started to adopt in that state has been thus far configured outside of the market mechanism as a socio-political constellation that does not have any competitor even if it intervenes in the market for macroeconomic ends. In this sense, Cerny names new state mechanism as competition state, detailing it: “as a state to promote a favorable investment climate for transnational capital, by providing a circumscribed range of goods and immobile factors of capital, including human capital, infrastructure, support for a critical mass of research and development activities; essential public services and maintenance of a public policy environment favorable to investment “(Cerny, 1995, p. 611). The competition state functions within a new domain of collective action in a global theatre since the rise of neoliberalism, together with Thatcher and Reagan administrations, also marks the shifts from national economies to the global economy. As Jessop (2007b, p. 187) points out, the emerging global “political-economic system represents a “new spatio-temporal-fix, a new social arrangement and socially-constructed institutional frameworks for the deferral of contradictions and crisis inherent in capitalism.” The states are still significant figures of political economy with their new positions to foster investments and new growth sectors and mobilize sources for a competition at the global level even if they are forced to retreat services as they had in the Keynesian welfare state.

In theory, the neoliberal political-economic system represents not only a particular regime of accumulation in the capitalist system, but it also involves an extension of market relations into the social world and its orders at the global level. The harmonies of both economic and non-economic factors are required to aim for establishing and sustaining global competitiveness. According to Jessop (2007b, p. 187) growth of new technologies based on the systems of innovation depends on “mobilizing social as well as economic sources of flexibility and entrepreneurialism, to penetrate into micro-social relations in the interests of valorization.” The emphasis on the extra-economic, micro-social aspects of the political economy that Jessop and Sum (2001) further extend it to the cultural political-economy provides a more in-depth analysis of the transformation of the state and the interdependence between the economic and social terrains. This analysis can be used in further analysis of how a hegemonic bloc is created through the mobilization of the social forces in a Gramscian perspective. It is also helpful to investigate micro-physics of power between the subjects. However, Cerny (2006, p. 685) disagrees and claims that whereas Jessop emphasizes non-Marxist theories that privilege socio-political variables, especially politically instituted market mechanisms, his most important arguments are still in line with economic determinism because of his adherence to Marxist theory. Hay (2004, p. 40), in a parallel vein, postulates that a new state regime of residual and competition state has theoretical advantages in terms of clarity and simplicity than Jessop's Schumpeterian workfare state theory. In fact, theories regarding the interrelatedness of social and economic forces can be deployed for more accurate analysis instead of avoiding them because of the fear of economic determinism and Marxist Orthodoxy.

Benefiting from Marxist terminology, not being an exponent of this theory, is Robert Cox, for instance, who points out that a historical structure is a picture of a particular configuration of forces, which are material capabilities, ideas, and institutions. There is a reciprocal and interactive relationship between them (Cox, 1981, p. 136). Cox accepts that ideas are the products of historical conditions, which seem at first sight that his evaluation is similar to that of Marxism about the illusive concept of the ideology. There is, however, an explicit nuance between Marxist terminology and Cox's formulation in that Marx in *The German Ideology* describes ideology with the "camera obscura" simile, which is an upside-down vision of reality (McLellan, 1995, p.154). In other words, Marx and Engels (1970) point out that ideology reflects an inverted image of social reality, which is distorted and false, whereas Cox merely accepts its conditionality as a result of objective social and historical conditions. Theoretically, unorthodox approaches that respond to the complexity of the factors affecting the changes in the world order can be articulated with Marxist terminology, thus resulting in a robust analysis instead of an economic determinist one.

The economic rationale behind biotechnology is closely related to how proponents of neoliberalism understand economic growth and locate technology-intensive new sectors as a catalyst to reach macroeconomic targets. Rooted in the searches for the remedies for the slowdown in the economic growth and concerns for a global recession, a new techno-economic paradigm has emerged. Nielsen (1991, p. 18) describes it as "a cluster of innovations, which involves completely new forms of work, new models of management, new locational patterns, and new high growth sectors." Based on this paradigm, technoscience and economic growth gained special status as crucial factors for the creation of national pride as well (Gottweis, 1998, p. 160). New domains grounded on new technologies for economic growth and new value creation emphasize the requirement for techno-scientific efforts to exploit the resources further to be used for the novel sectors. However, the scarcity of natural resources, such as minerals and fossil fuels, which have already come to the point that they are not reliable for sustainable growth, makes it impossible to set a future on resources that you are able to find naturally. In this sense, the artificial re-creation of nature (Rabinow, 2005), by ending the distinction between nature-nurture, provides a reliable basis to create an economic activity on biotechnology.

As a new sector, biotechnology stands at the intersection of techno-scientific activities of molecular biology and initiatives to produce biological commodities, in other words, it is at this intersection that "a new space for economic activity is created"

(Kenney, 1998, p. 131). Biotechnological innovations in agricultural production and biomedicine then represent tangible examples of this new economic setting. In this setting, new domains for economic value creation are constructed to realize the economic growth in more sustainable manners, as is the case in biotechnology, which remodels nature in a more perfect form.

Genomic sciences and biotechnology as a source of sustainable economic growth is less dependant on its technological capabilities for the discovery of new diagnostic and therapeutic techniques than the transferability of its discoveries into financial returns in the market. In this sense, cost management has become a crucial part of these new industries to ensure financial returns through knowledge production. Cooke (2002, p. 5) argues that "to the extent, genomics give rise to superior tests or drugs to those presently available at a comparable cost, knowledge is acting on knowledge itself to enhance productivity." However, the issue of affordability of genomic diagnostic and therapeutic tools is not a prerequisite itself for the market success of these medical products. Genomic pharmaceuticals are less likely to be affordable than conventional medications. Rather the crucial point is to assign value to novel medical products and convince potential customers about their superiority to existing products in the market. This is more urgent because the application of genomic techniques in health care practices is quite primitive (Khoury et al., 2011). The knowledge on which genomic diagnostic and therapeutic techniques depend is more valuable than the results of the application of these tools into medical practices. The constitution of the biotechnology sector, in an economic sense, beyond techno-scientific activities conducted at the universities, includes institutional ends to set a market and a function of the transformability of techno-scientific activities into knowledge market relations. Jessop (2007a) discusses the knowledge as a novel type of fictitious commodity with reference to Polanyi's (1957) original conceptualization of labor, land, and money as fictitious on the ground that they cannot be defined as commodities in essence even if they are exchanged in the market.

2.3) The development of genomics and governance mechanisms

The spatial reconfiguration of economic activity at the global level and new high technology sectors that are designed to increase the competitiveness of the nations to benefit from the global economy altered the political-economic scene. The publicly-funded initiatives were invested in new technologies under the conditions of globalization and the dominance of the neoliberal model. As a result, there was fierce competition among states to reap the benefits of new knowledge economies (Salter & Faulkner, 2011). There were general changes and the emergence of novel technologies in the various industries within the realm of biotechnology, therefore creating the question of the governance of these activities at states and transnational agencies level. However, the scope of this research will be limited to genomics and the new pharmaceutical industry associated with it.

Launched in 1990 and completed in 2003, administered by the US Department of Energy's (DOE) and the National Institutes of Health (NIH), Human Genome Project (HGP) is a publicly-funded research project to map human genes, which comprises an exact example of the investment into competitive economic sectors According to Cantor (1990, p. 49), the origin of the project dates back to a meeting in Alta, Utah, in 1984, where scientists questioned the possibility of sequencing human genomes, whereas the DOE has a congressional mandate to investigate inherited damage caused by low-level exposure to radiation. DeLisi (1988, p. 489), then the director of the DOE Health and Environmental Research programs and avid proponent of the project, linked the project with a meeting in 1986 in Santa Fe where participants from “industry, academia, and the national laboratories assessed of the technical feasibility of sequencing the human genome, the probable cost, and the potential benefits to the nation.” As can be seen in the emphasis in the last passage, in these technical meetings in the participatory phase of the project, cost, and returns of the sequencing human genes were also debated in addition to scientific points. These debates on the cost of the project and potential benefits for the US economy also constituted the market logic of genomics part of biotechnology. After the discussions, the project was launched with 3-billion-dollar federal funding. Fortun (2008, pp. 51-4) argues that the main goal and underlying logic of the HGP are not to fully sequence human genomes, holy grails of human genetics, rather to create an infrastructure for more efficient genomic technologies to be used in medicine and pharmaceutical industry for diagnosis and treatment options. He states that a US-centered genomic economy that would be dominant in a competitive global bioeconomy was one of the pivotal reasons for federal spending on the project.

After completion of the research, the economic impacts generated through the project went well beyond the scientific discoveries during the research. According to a report prepared by Tripp and Grueber (2011, p. 15) for the Battelle Memorial Institute, a private science and technology development company headquartered in the USA, “whereas the federal government invested $3.8 billion in the HGP through its completion in 2003, the human genome sequencing projects, associated research and industry activity—directly and indirectly—generated an economic impact of $796 billion, personal income exceeding $244 billion, and 3.8 million job-years of employment between 1988 and 2010”. The updated figures on Battelle’s website were published on 12 June 2013. According to the new report called the Impact of Genomics on the US Economy, “the HGP and related research continue to yield significant US economic growth with a $965 billion in impact, more than 53,000 direct genomics-related jobs and $293 billion in personal income, leveraged from a total federal research and development investment of $14.5 billion from 1988 through 2012”. In the last instance, the HGP paved the way for the new projects of genetic research and the primary settings of the pharmacogenomics sector. The further initiatives were facilitated by the technical means and understanding in parallel with the HGP that conceptualizes the human biological material as a new kind of commodity to be processed for the generation of more value through public and private agencies. In this sense, the HGP goes beyond being a mere scientific project with humanitarian purposes to fight against hereditary cancers and complicated disorders.

Global competitiveness in the biotechnology sector dominated the HGP since its start. The competition in biotechnology involved new players in addition to the states. Economic competitiveness in knowledge-based technologies was required to support the biotechnological revolution through the foundation of new companies. The start-up biotechnology companies, located in San Francisco Bay Area, Delaware-Maryland region, and Massachusetts, were funded increasingly by venture capitalists because of the expectations of high return from the emerging US biotechnology sector in the 1990s. Newly biotechnology companies like Human Genome Sequences Inc., established in 1992 in Maryland, Incyte, established in 1991 in San Francisco Bay Area, and Millennium Pharmaceuticals, established in 1993 in Cambridge, Massachusetts, managed to develop innovative models using bioinformatic systems to mine genetic information and to get profit through a partnership with pharmaceutical sector giants like Pfizer, Hoffmann-La Roche, Glaxo (Fortun, 2008, pp. 40-41). In that period, several biotechnology companies diversifying their area of operations have invested in the development of technology for mapping and sequencing. For instance, companies like Applied Biosystems of Foster City, California, and DuPont, of Wilmington, Delaware, focused on automated sequencers (Ackerman, 1988, p. 18). Among new investments in the biotechnology, the most prominent one was the Celera Genomics, founded in 1998 by Craig Venter, who previously attempted to patent the stretches of DNA while working for the NIH (Rabinow, 2009, p. 85). Celera Genomics challenged the HGP by developing its genome sequencing project because the opportunities to patent the discoveries within the HGP were limited. However, while approaching the completion of the HGP, then US President Bill Clinton succeed in negotiating Venter with the administrators of the public project, therefore ensuring the full collaboration of the parties. Venture capital and public-funded investments in biotechnology companies help the US maintain its dominance in the competitive global economy as discussed and planned before the HGP.

The global competition and the dominance of the US in the emerging biotechnology sector encouraged the other nations to follow the American experience as a model in order to compete or at least collaborate with the US, aiming at benefitting from new technologies. As Fortun (2008, pp. 36-37) exemplifies Jack McConnell's statement, who helped draft the early US legislation on the HGP as an officer of the pharmaceutical company Johnson & Johnson, about the HGP and its targets. For him, the primary target of the project was to support the US biotechnology and pharmaceutical industry, therefore keeping America competitive rather than understanding the genetic code of humanity. In this sense, the US model for the competitive advantage in biotechnology is an example of the mobilization of the sources and actors for the desired end. The timely investment into sustained competitiveness, as discussed by participants from the state agencies, industry, and academia, and flexible regulatory environment enabling the patenting of the discoveries of genomic research together with academia-industry collaboration.

The public expenditure to support the biotechnology sector in the USA generated a multiplier effect, which enables this sector to extend further into global markets. Indeed, the European Community attempted to create world class competitors in R&D-intensive, high value-added, and high growth sectors targeting areas of information technology; manufacturing technology; telecommunications; biotechnology; new materials; and marine science and technology (Jessop, 1993, pp. 22-23). However, the technological expertise of the US in biotechnology, their competitive advantage forced European biotechnology companies and European Community agencies to establish strategic alliances with US companies. For instance, The European Steering Group (ESG) was established in 2014 within European Community European Innovation Partnership on Active and Healthy Ageing, bringing together representatives from the policy environment and civil society, healthcare professionals and scientific societies, academics, and industry; the group that searches for sustainable health programs for European people was, however, technologically supported by AbbVie, an American publicly-traded biopharmaceutical company, as a partner of the project. Birch (2006, p. 95) points out that huge US federal funding on biotechnology investment is an important factor for the global success of American biotechnology companies in the sector. In turn, the European pharmaceutical companies collaborated with US companies instead of national biotech firms in their home countries.

The mythical status of the US biotechnology sector that Gottweis (1998, p. 159) observes also has consequences on the regulation of the sector. The regulatory environment in the US facilitating the development of the biotechnology industry, such as The Bayh–Dole Act or Patent and Trademark Law Amendments Act, which was adopted in 1980, motivates the EU to pass similar laws to keep their competitiveness. Birch (2006, p. 107) claims that the efforts in other countries, especially in the EU, create an impact on the regulatory structure of the other nations toward weaker regulatory schemes, thus resulting in a cycle of less strict regulations and more competitive capacity. Therefore, the biotechnology sector grows at the global level within a discourse of competitiveness and repetition of the development model of the American biotechnology sector.

There is no pure private or public research under the neoliberal model. The shift in the role of the state mechanism to foster new innovative sectors and academy-industry collaborations are the main factors in the hybridization of the research domain. In this sense, population-based genetic research and biobank databases are associated with the projects that public agencies consider when funding projects. These projects need to have a solid financing model and to fit into the national innovation system and its characteristics, such as the availability of venture capital or the structure of the pharmaceutical industry (Gottweis & Lauss, 2012, p. 66). Deciding on the projects as significant expenses of the public budget, the notions with medical contents should also be considered within policy-making processes. As a crucial term, "clinical utility," for instance, refers to the likelihood that a given intervention, genetic information, will lead to improved health outcome or to whether a test can provide information about a diagnosis, treatment, management, or prevention of a disease that will be helpful to a consumer (ACMG Board of Directors, 2015, p. 505). In this sense, the investment into a genome project is expected to produce a utility in a clinical sense. Becker et al. (2011, p. 9) cite the resolution of the European Society of Human Genetics in 2003, according to which "beyond the rare Mendelian subsets, genetic influences in common diseases are likely to be conditional on the environment, while testing for these low penetrance susceptibility genes is likely to be of limited clinical utility." In this sense, environmental factors continue to be factors that are not taken into consideration in genetic determinist approach to the roots of diseases, whereas this approach constrains itself in terms of clinical utility. The research on the genetic roots of cancer comprises a significant portion of total genetic research. However, only 5–10% of all cancers are due to an inherited gene defect. Most cancers are not of hereditary origin. Lifestyle factors, such as dietary habits, smoking, alcohol consumption, and infections, have a profound influence on their development (Anand et al., 2008, p. 2098). The correlation between the disease, environment, and gene mutations as a part of clinical utility interwoven with economic value and public budget targets, therefore resulting in a severe challenge to policy-making.

2.4) Institutional Settings

The fostering of new high-technology economic domains and investments into these sectors were supported by international organizations and governance bodies as well. These institutions acknowledged and encouraged investments into knowledge-based economies as the model for economic growth and supplementary policy targets such as sustainable health. The entrepreneurial society is encouraged in this way, which is also the social ethic of enterprise that Weber, Sombart, and Schumpeter tried to write the political, cultural, and economic history (Foucault et al., 2008, p. 147). The global conjecture, the development model, and the aims to incorporate new knowledge production into society endorsed by these organizations. New subjectification processes are conducted with the diffusion of the social ethic of the enterprise (Foucault et al., 2008). As a result, individual conduct is shaped on the basis of the discourse of rational subjects.

The popularity of the knowledge-based economies is related to the revival of the Schumpeterian theory in the 1990s and the advocacy of international organizations on his arguments. Godin (2006, pp. 17-18) claims that the knowledge-based economy as an umbrella concept serves of policy-makers to science and technology issues and to their role in the economy. He also adds that this concept owes its salience to efforts of the Organisation for Economic Cooperation and Development (OECD). Although his definition of the knowledge-based economies as a tool involves minimal insight into how the concept of knowledge-economy functions to mobilize social and economic forces, his argument about the role of t the Organisation for Economic Co-operation and Development (OECD) is quite appropriate. Indeed, neo-Schumpeterians, including Freeman and Perez, have been highly influential on the policy-making for industrial policies and technology programs, both at national and the level of international organizations, mainly the OECD (Nielsen, 1991, p. 20). Pyka et al. (2009, p. 5) observe that through the efforts of the OECD in the 1990s, Schumpeterian principles of innovation and technical change became dominant in the growth policies.

The OECD publication titled “Knowledge-Based Economy” (1996) has a feature of the manifesto about the role of knowledge-economies in the global political economy and its function as a solution to the crisis in the 1970s in parallel with the Schumpeterian approach. According to this publication (1996, p. 7), the “OECD economies should maximize performance and well-being in knowledge-based economies for the production, distribution, and use of knowledge and information, in parallel with the new growth theory that affects the role of knowledge and technology in driving productivity and economic growth.” After the affirmation of the role of the knowledge and innovation in economic growth, Knowledge-Based Economy (1996, pp. 35-36) classifies high-technology, high-growth sectors including computers, communications, pharmaceuticals, and aerospace. In this sense, investments in these sectors have a higher capacity for economic growth and employment with higher wages. This model also has social implications beyond economic growth and productivity. As per the document (1996, p. 25), “the science system must balance not only its roles of knowledge production and transmission but also the transferring of knowledge to economic and social actors, enterprises, through the linkages between the science system and the private sector to speed knowledge diffusion.“ In this framework, the university/industry collaborations and associated economic issues such as exclusive licensing, intellectual property rights, equity ownership are the keys to diffuse knowledge into society.

The OECD specifically discussed the future of the bioeconomy in 2009 as well. In a publication called “the Bioeconomy to 2030 Designing A Policy Agenda. Main Findings and Policy Conclusions” the organization mainly focused on three sectors: agriculture, health, and industry. The principle policy conclusions of the document regarding health sector emphasize the requirement of translating new technologies into health systems, proceeding scientific research on population-based medical research through further funding, and enabling the participation of citizens into public dialogues to ensure the legitimacy of the scientific efforts. According to the document (2009, p. 6), “a costly but beneficial revolution in healthcare, some emerging technologies, such as regenerative medicine and personalized and preventive medicine, could require far-reaching changes in healthcare delivery.” The accord of the private sector developing health therapies with the public interest, regulatory systems regarding healthcare incorporating pharmacogenetics, the support long term research, population-based medical databases, and the dialogue with the public on the future benefits of biotechnology are the significant recommendations of this publication.

The salience of human genomics as a particular branch of the bioeconomy was also emphasized by the OECD in “Genomics and The Bioeconomy Symposium” in 2010. In the event jointly organized by the OECD, the Human Genome Organisation (HUGO), the McLaughlin-Rotman Centre for Global Health of the University of Toronto, and the Mexican Health Foundation (FUNSALUD), the opportunities of modern genomics and the historic achievement in human health in the ten years since the first draft sequence of the human genome were discussed. In the conclusion of the symposium (2010, p. 16), the development in medicine and biology were described as the possibility for humanity to transform health, industry, agriculture, the environment as well as the economic status of mankind in general.

Other international organizations have also been involved in the policy suggestion for new knowledge-economies and their application into medicine, such as the European Union, the World Economic Forum, and the World Health Organization. The European Steering Group (ESG) for Sustainable Healthcare, which was supported by the US biopharmaceutical company AbbVie and chaired by Former Health Minister of Ireland, Mary Harney, published a pan-European White Paper Acting Together Roadmap for Sustainable Healthcare in 2015. During the preparation of this document, the ESG met regularly and organized roundtable meetings with high-level policy stakeholders at the EU level, including representatives from the European Commission, the Council of Ministers, and the European Parliament. The 18 recommendations put forward by the group focus on three main themes, prevention, and early intervention, fostering the empowered and responsible citizen, and re-organization of care delivery.

According to the White Paper (2015), the steps for sustainable healthcare are summarized as “investing in prevention and early intervention, fostering empowerment and responsibility in citizens and reorganizing care delivery." To do so, the monitoring of the health trends and data collection; the establishing a new data protection rules and regulations, the stronger engagement of employers and health professionals in the field of occupational health, the tackling with the health illiteracy, and the support of new technologies for the transformation of healthcare were also suggested. In these suggestions, besides the protective environment for the biotechnological investments into health systems, the rationale of neoliberalism at the individual level, the empowerment of individuals was also underlined. Empowerment and tackling health literacy are crucial points to create consumers for the products of the pharmacogenomics industry that will be integrated into health systems. Underscoring individual autonomy conforms with the neoliberal discourse of rational individuals who will pursue their biological enhancements with their own choices.

The emphasis on the requirement to increase health literacy functions as an opportunity for the diffusion of the patient empowerment discourse as well. The need for education was highlighted within academia and international organizations, pointing out different scopes and target groups. For instance, Chapman et al. (2019, 81) propose a comprehensive education program that includes the training of teachers, doctors and nurses, psychologists, and other professionals on genetics. The World Economic Forum Report (2013, p. 16) emphasizes the need to improve health literacy at every age, starting with schoolchildren, in order to address the change in social values and to change how we think about and value health in the age of precision medicine. An OECD Report titled *Health Literacy for People-Centred Care* associates health literacy with the ability to make informed decisions about the care options, engage in preventive measures, and take greater responsibility as empowered patients

(Moreira, 2018, p.10). In these narratives, the responsibility of education on health literacy is articulated within neoliberal discourses as public policy targets.

The report of another international organization, the World Economic Forum, also addresses the problems in the transformation of healthcare. The report prepared in collaboration with McKinsey & Company, a global management counseling company, titled "Sustainable Health Systems Visions, Strategies, Critical Uncertainties, and Scenarios Healthcare Industry" (2013) points out three main actionable points. These are "to embrace data and information to transform health and care, to innovate healthcare delivery, and to build healthy cities and countries of the future." In this framework, precision medicine as a new technology in medicine, was particularly underlined. The World Economic Forum Report also mentioned lifestyle changes as a crucial part of living in a healthy way in addition to the requirement for empowered individuals, which indicates how new technologies in medicine function as biopolitical techniques to shape individual conduct while organizing economic activity under the neoliberal model.

The World Health Organization (WHO), through its publication on its website titled "Human Genomics in Global Health," is another international organization that mentioned the technological and scientific innovations in medicine as well. According to this publication, these innovations have the potential to influence the standard of health of people through genomic techniques in medicine and to contribute to economic development through better management of the diseases. In this setting, the financing of genetic research, patenting and intellectual property issues, equitable access and affordability of genetic information and services, raising the level of public awareness on genomics, and ethical standards in genomics were mentioned as the challenges to be addressed by policy-making. The WHO further emphasizes the need for the global collaboration of the effectiveness of new technologies in health practices and evaluates the application of these techniques in the emerging economies with a global perspective. Whereas Cuba, Brazil, India, China, and South Africa were exemplified as the well-functioning examples in the application of genetic technology and services to the health needs of their populations, the need for further global cooperation through the exchange of the health information was highlighted by the WHO.

2.5) Conclusion

Genomics, as a field of inquiry, and biotechnology, in general, were designed as new economic activities in parallel with shifts as a result of the neoliberal model. On the one hand, fostering of new high technology sectors by competition states accelerated the investments into this sector. On the other hand, the new regulatory environment developed synchronically enabled parties involved in research processes to patent their scientific discoveries as a result of academy-industry collaborations. The biotechnology projects were supported by states with generous funding to create a new economic domain for the maintenance of competitiveness. For instance, in the case of the HGP, the project aimed at the protection of the US biotechnology and pharmaceutical sectors' dominance in the global political economy. The federal funding of the project and the flexible regulation encouraging the property rights on the scientific discoveries created proliferated outcomes through the multiplying effects of the initial public expenses. In this way, the HGP not only did generate genomics-related businesses and employments, and the stock market successes of biotechnology companies in the domestic market but also spread these activities to the global markets. The perception of the superiority of the US biotechnology sector, which is caused by massive funding, forced other countries to collaborate with the US companies, such as the policy-making efforts of the European Steering Group (ESG) for Sustainable Healthcare throughout the European Union in collaboration with the US biopharmaceutical company AbbVie, while there was fierce competition in the biotechnology sector to move forward among the countries The investments into new high technology sectors and the development model based on innovative sectors were strengthened with the involvement of the international organizations, mainly the OECD, in policy and opinion-making processes, by endorsing a knowledge-based economy model.

The knowledge-based model and similar discourses on entrepreneurship have also served as a means to create discourses for social control and regulation. The social ethics of enterprise and the role of science and knowledge in economic development laid the foundation of the social shifts. Because of new political-economic discourse, it is the new field of concomitance that praises the growth and advancement of science (Gottweis, 1998, p. 160). In parallel with this Foucauldian argument, the analysis of the newly emerged economic activities, domains, institutions, and governance alternatives needs to take the discourses producing these into consideration. In this sense, the advance of molecular biology, which finally realized its full potential in genomics science, was designated to create a science of man for consensus formation and cultural hegemony since the efforts of the Rockefeller Foundation starting in the 1930s (Kay, 1998, pp. 22-23). The social regulation comes into sight with a new form to influence the opinion-making in parallel with the principles of the new discourses of political economy.

The rationale behind biotechnology and genomics, in particular, as new economic activities diffuses into individual conduct through discourses. The economic model of neoliberal development theory relies on the Schumpeterian principles of innovation and structural competitiveness (Jessop, 1993). After the affirmation of these notions as superior values on which the construct discourses, the non-coercive character of the neoliberal governmentality produces identities and subjectification processes through the discourses. Within the context of genomics and healthcare, rational subjects invest in their health as entrepreneurs of their personal enhancements. Therapeutic and diagnostic products of new medicine represent the innovative aspect of science. It is imperative to pursue new genetics and medicine for self-realization and the maintenance of individual competitiveness in society.

CHAPTER THREE-THE ICELANDIC GENOME PROJECT

3.1) Overview

This chapter discusses the population-based genomic research in Iceland conducted by the private sector company deCODE Genomics. In this context, the political-economic circumstances and the legal framework that enables this company to mine the Icelandic gene pool for economic benefits are examined. The neoliberal economic model is the context for the incorporation of deCODE Genomics to make investments in Iceland and the Health Sector Database that set the appropriate regulative atmosphere. The entrepreneurial model in the Icelandic genome project was implemented by a public-private partnership and managed to articulate individual conduct with the targets of the project. In the articulation of the micro-level with the project, the discourses of contribution to the local economy and the protection of national values, the Icelandic genealogies, and gene pool, through better technological means, played crucial roles.

Iceland was an ideal place to invest because of the combination of genetic homogeneity of the population and its public health infrastructure. This combination enticed investors and researchers with medical records of the country, which could create more accurate pedigrees to examine the roots of the diseases. Together with the blood samples collected from Icelandic people during the project and the genealogies in Icelandic society dating back to as early as the ninth century, generate comprehensive data at the service of the project. The combination of genetic and genealogical data generated a great economic value reaped by private-sector enterprise and venture capitalist firms. The efforts of the medical experts who were excluded from participating in the policy-making resulted in the collapse of the database project. In the end, the economic value created from the Icelandic gene pool did not any contribution to the local economy as promised, whereas the efforts to construct the database turned into a massive biopolitical project.

The global-level developments are highly decisive in the initiatives for the project. On the one hand, a new economic growth model propelled by neoliberal policies and governmental bodies encouraged investments in knowledge-driven high technology sectors, including biotechnology. On the other hand, a new approach to medicine, which focuses on the genetic roots of the diseases, increased the sources dedicated to population-based research projects because of the prospected diagnostic and therapeutic innovations through genome-based knowledge. In parallel with these factors, the launch of the HGP, along with a trend towards personalized medicine, were both supported with public funding and then by venture capital investments. As a result, new economic activities were created, which fostered further research targeting new locales and product development.

The Icelandic genome project is also a consequence of the local dynamics shaped by global economic trends. The 1990s were a turbulent period for the primary Icelandic fishing industry. In their collaborative article, the Icelandic anthropologists Helgason[1] and Pálsson examine the implementation of the systems of individual transferable quotas (ITQs). These quotas were first implemented in 1984 following the cod wars with the UK and extended further into the Icelandic fishery during the 1990s. The ITQs not only represented the commodification of fishing rights, an introduction of the market-oriented monetary exchange into the traditional understanding of the collective rights over the fish but also created social tensions, such as a national strike

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[1] Helgason was then employed as the head of the anthropology section in deCODE Genetics in 2000 as well as his affiliation with the University of Iceland.

of Icelandic fishers protesting against the ITQ system in 1994 (Helgason & Pálsson, 1997, pp. 452-59).

The socio-economic disturbances of the fishing industry and the expansion of free market economy mechanisms into this isolated island nation in the middle of the North Atlantic Ocean generated an impetus to seek alternative ways of value production. The global economic trends towards investments in novel biomedicine and gene studies and local economic transformations converged in Iceland as genomic research. As Rose (2007, p. 150) indicates, Iceland is a site where the logic of new biomedicine and new techniques for molecular interventions to generate novel relations between life and commerce can be found. Despite this explicit transition in the Icelandic economy, Pálsson and Hardardóttir compare the biogenetic databases in Iceland with fisheries. In parallel with the importance of fishing for the national economy, as a new source of economic growth, the biomedical sector may have benefitted from the history of property rights in fishing, which integrate commercial and communitarian perspectives, to develop alternative property regimes regarding the human genome (Pálsson & Hardardóttir, 2002, p. 285). In this sense, the economic benefits through property rights on the Icelandic gene pool are affirmed insofar as an equilibrium between the private and public interests is maintained.

3.2) The saga of deCODE Genetics and the HSD

deCODE Genetics is an example of a comprehensive genome project that fits the patterns of global venture capital firms targeting genetic studies as new sources of high profit. deCODE Genetics Inc. was incorporated in Delaware, the USA, in 1996. As a parent company, it owns a subsidiary that fulfills its operations in Iceland, the name of which is Islensk erfdagreining ehf., registered in Reykjavik in 1996. According to the Company Registration S-1 Document filed to U.S. Securities and Exchange

Commission for the initial public offering of the company on March 8, 2000, the cofounders of the company are Kári Stefánsson and Jeffrey Gulcher. Stefansson began as the President, Chief Executive Officer, Secretary, and a Director of the company in August 1996 and was appointed to serve as the Chairman of the Board of Directors in December 1999. Stefansson held a number of positions in academia and medical practice, including faculty positions in the Neurology, Neuropathology, and Neuroscience Departments at Harvard University and the University of Chicago, and the directorship of Neuropathology at Beth Israel Hospital in Boston, Massachusetts. Gulcher served as the Vice President of the company responsible for Research and Development. Gulcher also had past experiences in the Department of Neurology at Beth Israel Hospital in Boston, Massachusetts, and Harvard University Medical School. As such, the company was the scientific enterprise of two medical doctors who had worked together at Harvard University Medical School and decided to set up a company in Delaware because of the favorable tax exemptions. However, a closer look at the directors of the company and their affiliations shed light on the crucial features of this start-up company.

four out of seven venture capitalist companies that invested in deCODE had their representatives on the board of directors. Jean-Francois Formela[2] has served as a director of deCODE since August 1996, and as a member of the Audit Committee since February 1998. Formela is a General Partner of Atlas Venture Associates II, L.P. Andre Lamotte[3] has served as a director of deCODE since August 1996 as a

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[2] Before joining Atlas Venture in 1993, Dr. Formela was Senior Director, Medical Marketing and Scientific Affairs at Schering-Plough in the U.S. where he also held biotechnology licensing and marketing responsibilities.

[3] In 1989, Dr. Lamotte founded Medical Science Partners, or MSP, which specializes in early stage life sciences investments, in affiliation with Harvard University, and has served as the Managing General Partner since then. Before founding MSP, Dr. Lamotte served as a General Manager at Pasteur Merieux from April 1983 to April 1988.

representative of Medical Science Partners. Terrance G. McGuire has served as a director of deCODE since August 1996 and as Assistant Secretary since January 1998. Since March 1996, he has been a Founding General Partner of Polaris Venture Partners, who was a general partner of Alta V Management Partners L.P. Guy P. Nohra[4] has served as a director of deCODE since August 1996. He is a founder and general partner of Alta Partners, a venture capital investing in information technologies and life science companies. Despite the professional management team assigned by venture capitalists, as Fortun (2008, p. 198) points out, the company itself, and Kári Stefánsson individually, emphasize being an Icelandic company. The rhetoric of the involvement of local researchers in the project was also deployed in the Newfoundland case. However, the Icelandic genome project was portrayed as a contributor to the Icelandic identity articulating the project with the nationalist pride on the unique Icelandic gene and the tradition of family histories.

The initial public offering of deCODE Genetics exhibits the role of the venture capitalist through managers affiliated with the venture capital firms in charge since the establishment of the company. The method of the financing of the deCODE in the early stages makes these relations more obvious. The company was formed with a $12 million initial capital funded by seven venture capital firms, which are Advent International, Alta California Partners, Arch Venture Partners, Atlas Venture, Falcon Technologies, Medical Science Partners, and Polaris Venture Partners (Greely, 2000, p.165). As of 31 December 1999, Alta California Partners and Atlas Venture each hold % 7.1 percent of the shares of the company, whereas Polaris Venture holds % 5.7. In

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[4] Prior to founding Alta Partners in 1996, Nohra was a partner of Burr, Egan, Deleage & Co., which he joined in 1989 and served as a Vice President from 1989-1997. Previously, Mr. Nohra was a Product Manager of Medical Products with Security Pacific Trading Corporation, where he was responsible for a multi-million dollar product line and traveled extensively in Korea, Taiwan, Hong Kong, China and Southeast Asia.

addition, the representatives of venture capital firms are also stockholders of the company by themselves, with the following shares: Formela % 7.1, Lamotte % 2.1, Nohra % 7.1, McGuire % 5.7. There are also Icelandic shareholders of the company holding more or less % 1 of the shares of the company. These shareholders are Hannes Smarason[5], Executive Vice President and Senior Business and Finance Officer, Kristjan Erlendsson[6], Vice President for Clinical Collaborations, and the Vice President of Medical Informatics Sigurethur Bjornsson, who previously served as the Chief Executive Officer of an Icelandic investment company. Their presence served to strengthen the argument of an Icelandic enterprise investing in Iceland as well.

deCODE successfully attracted direct capital investment because of the efforts of Kári Stefánsson while he has been working in the USA in the early 1990s. According to Zoega, chief psychiatrist of the National University Hospital in Iceland, and Andersen, an assistant professor from the School of Medicine at the University of California in San Diego, Kári Stefánsson involved in discussions with investors Kevin Kinsella. In a letter to Stefansson dated May 16, 1995, Kinsella[7] summarizes the idea, resulting in the genome project in Iceland:

> As we discussed, Iceland is perhaps the ideal genetic laboratory since there has been virtually no immigration (lots of emigration, of course); it is of manageable size (200,000+ inhabitants), is an island expected to have many founder effects, has high-quality national healthcare-from which we can expect excellent disease diagnosis, has formidable genealogies, and the population is Caucasian-of most interest to pharmaceutical companies.
>
> What we would propose to do, in partnership with you, is sponsor a massive program to identify probands in the entire Icelandic population, collect blood from the entire population, establish pedigrees for important complex genetic

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[5] Smarason had a background in McKinsey & Co. in Boston as a consultant.

[6] Erlendsson is a medical doctor with an educational experience in the USA and the former Director of Hospital Affairs at Iceland's Ministry of Health and Social Security before joining the company.

[7] Kinsella, then the became of the president and chief executive officer of Sequena, a genomics company operating in La Jolla, California, known for its research on genetic causes of asthma, which was accused of "biopiracy" because of the research in Tristan da Cuhna, a small island in the South Atlantic whose 300 person population is derived largely from Scottish families (Greely, 200, p. 164).

> diseases, genotype members of the pedigrees, conduct linkage studies on the disease and positionally clone the genes of interest (Zoega & Andersen, 2000, p. 38).

Prior to the project, there were efforts by the founders of deCODE in order to engage with Icelandic patients and research subjects. Hilary Rose (2001a, p. 8) relates the origin of the Icelandic genome project to the summer of 1994 when Stefánsson and Jeff Gulcher visited Iceland to collaborate in a study of genetic disposition to multiple sclerosis (MS) with an Icelandic neurologist, John Benedikz. The link between the studies of the duo with Icelandic MS patients and the flow of events towards a comprehensive genome project is more meaningful than it seems at first glance. Fortun (2001b) points out the Settlement Agreement between the Beth Israel Deaconess Medical Center (BIDMC), where Stefansson worked from 1993 to 1996, and deCODE Genetics. According to the agreement, Stefánsson's scientific findings of genes associated with multiple sclerosis, arrived at by using facilities and resources of BIDMC since 1993, would be jointly owned by both parties. The engagement with Icelandic patients before the project, regardless of the commercial value of the discoveries of the research, enabled the founders of deCODE to mention these studies as tributes to the homeland. Sigurdsson (2001, p. 113), who is a historian of science from the University of Iceland, indicates that while patients' groups did not play a large role in the Health Sector Database and deCODE controversy and there have been no further genetic findings about the MS disease, Stefánsson's work with the patients in Iceland was used to support their claims during the debates about the HSD going forward.

In the preparation period to the HSD, deCODE's effort to obtain financial support and, therefore, popularity in Iceland were crucial to achieving the targets of the company. The most significant achievement of this period is the certainly research collaboration and a cross-license agreement signed with the pharmaceutical giant

Hoffmann-La Roche on February 1, 1998. According to this agreement, Roche and deCODE would collaborate to discover genetic variations that affect the pathogenesis of diseases and to develop new methods for diagnosing f diseases and drug discovery. As stated by the company in the S-1 document, deCODE may receive a total of more than $200 million in equity contributions, research funding, and milestone payments. This agreement covers research of up to twelve disease categories over a period of up to five years. The agreement gives Roche exclusive rights to develop and commercialize therapeutic and diagnostic products based on gene discoveries, whereas Roche will provide the Icelandic people free of charge with pharmaceutical and diagnostics products that emerge from the collaboration. Following the agreement, Roche has made capital investments in deCODE, Roche Finance Ltd, or Roche Finance, an affiliate of Roche, has purchased shares of Series C preferred stock, has also purchased warrants to buy shares of Series C preferred stock and has an option to purchase additional shares. As a result of these transactions, Roche became the biggest single shareholder of the company with 4.483.334 shares as of 31 December 1999, according to the S-1 document filed by the company.

deCODE’s success in attracting capital venture investment was also a crucial indicator of its ability to conduct such a comprehensive project. Through this agreement, deCODE strengthened its position in Iceland in the minds of politicians and indirectly the Icelandic people (Árnason & Wells, 2003). The symbolic presence of the Prime Minister of Iceland, David Oddsson, during the signing ceremony, the agreement, is also an indicator of the trust of politicians to deCODE’s future plans in Iceland (Sigurddson, 2001, p. 105). Iceland has also started to become a global phenomenon through the power of the media. The reactions of the international media agencies to the Icelandic genomic research accelerated with Roche agreement were both sensational and also contained arguments of the support by the Icelandic authorities. For instance, an article published on BioWorld Today included the David Oddsson's statements to support the foreign investment into the project: "It is extremely important for us to secure foreign investment in Icelandic companies, and I am delighted to see an investment of this size in a high-tech venture in our country" (Moran, 1998). The similar sentiments of Iceland's Prime Minister mentioning the agreement "as a huge step towards securing an important role in the Icelandic economy for high-technology industries" hit the headlines in various biotechnology publishers (The Pharma Letter, 1998). provocative articles, even in journals with high reputations, made Iceland's gene pool and deCODE Genetics known worldwide. One of the most striking examples of these attention-provoking articles is "Natural-Born Guinea Pigs" by Gibbs in the Scientific American in February 1998. The author defines the Icelandic population pejoratively as "270,000 citizens of this island nation, a great majority of them descended from seventh century Viking settlers, form one of the most inbred populations in the World". The partnership with a global player in the pharmaceutical industry enhanced the appeal of the project and the Icelandic gene pool in addition to the strategic deals between the parties.

The global attention increased deCODE's financial capacity through further options such as public offering, providing the company with tools for speculative actions as well. According to Zoega and Andersen (2000, p. 37), after the signing of the contract, the value of the shares was around $5, and the total value of the deCODE was around $120 million. Before the launch of the deCODE's shares publicly trade in NASDAQ in July 2000, on June 30, 1999, deCODE entered into a Stock Purchase Agreement to sell five million shares of the company to a Luxembourg-based financial buyer, Biotek Invest SA. Five million of deCODE's shares were bought by a consortium of Icelandic banks and other financial entities for between $16 and $17 per share. The banks then sold about 40 percent of these shares to Icelandic investors (Greely, 2000, p. 169). The shares subjected to this sale belong to the venture capitalists who paid $1 per share in 1997, although they are bought by Icelandic investors for approximately $16,50 per share, which sharply fell and never took off again (Arnason, 2007, p. 7). Furthermore, according to an article in Iceland Review (2005), the stock traded for up to $60 on the Icelandic gray market from 1998 – 2000; the article also questions the transactions to Luxembourg subsequently dissolved through Panama. As Fortun (2008, p. 259) indicates, six thousand Icelanders exposed the financial risk at the bottom of the speculative chain for the genomic slot-machine that they paid $65 to pull the handle in the case of this stock speculation.

Following the success of the Roche agreement, deCODE Genetics applied to the Icelandic government to demand the regulatory environment and the political support that they needed to launch operations for a comprehensive genome project. The first introduction of the bill in 1999 created considerable controversy and shed light on the aspect of relations among the company and politicians. However, Gardar Arnason (2007, 7) claims that deCODE, prior to explicit political debates, had been negotiating the bill with the Icelandic government, particularly with Prime Minister, Oddsson, and the Minister of Health, Pálmadóttir, since 1997 in a confidential manner. Moreover, Sigurddson (2001, 112) points out that the draft bill had been faxed by deCODE to the Ministry of Health and Social Insurance at the beginning of September 1997. His argument is based on a quotation from “Kári í jötunmóð” a book written in 1999 by historian Gudni Thorlacius Jóhannesson, who has been the President of Iceland since August 2016. The Prime Minister’s endorsement on the agreement with Roche, which is very clear because of his presence during the signing ceremony, shows the importance of foreign investments in the high technology-driven economic sector. In addition, the first female President of Iceland, Vigdís Finnbogadóttir, was recruited by deCODE as a board member to strengthen the nationalistic discourses embedded into the project.

One of the vital points for political articulation is the support of the prominent public figures to the project. For instance, Finbogadottir, the first and only female President of the country, was recruited as a member of the board of the company. She had spoken frequently of the need for high-tech jobs to bring young Icelanders home during her presidency, in line with the center-right government of Oddsson's enthusiasm for the new company. (Rose, 2001a, p. 16). deCODE's promises of high technology investments into the country and contribution to the local economy accelerated the process of policy-making. As Vilhjálmur Árnason and Gardar Árnason (2004, p.173) state, proponents of the bill, in particular, the Prime Minister and the conservative MP Olrich, were in favor of a speedy process to conclude the debates about the formation of the HSD. The quick action was crucial because the market opportunities which made the database project feasible for a private company might suddenly evaporate in the volatile and fast-paced world of biotechnology and genetics. The ideological compliance between the deCODE targetting a market-based system for a health-related service and the center-right government that sees the foreign investments in the high-technology sector as a solution for the troubled economy following the turmoil in the fishing sector is a catalyzer for the HSD.

The Health Sector Database bill was first submitted to the Althingi, the national Assembly of Iceland, in March 1998. After the announcement of the draft bill publicly, a plethora of debates started both at the national level and the international level, and various platforms. According to the draft bill, the licensee would be authorized to connect data from two other databases: a database with genealogical information that has been processed from public genealogical records and a database of genetic information that is processed from biological samples obtained for research by physicians cooperating with deCODE Genetics as well as the HSD based on the medical records itself (Árnason, 2010, p. 299). The Health Ministry was forced to withdraw the bill a month later, after fierce opposition from the Icelandic Medical Association and a unanimous appeal for postponement by the staff of the University of Iceland's Faculty of Medicine. The points that they criticize can be summarized as the storage of personal information without prior informed consent, the idea of the monopoly of a company over commodified medical records instead of being a collective property of a whole nation as Enserink (1998, 890) indicates.

In addition to sessions in the Althingi, the proponents of the database legislation, mainly the representatives of the government and the deCODE, and opponents of it, mostly physicians and academicians, discussed their arguments in local and international journals. Representatives of the Icelandic Cancer Society, the Institute of Biology, the University of Iceland and the Icelandic Medical Association focused on the scientific, ethical and economic issues caused by the database model based on the monopoly of a private economy and perception of medical records as the commercial assets and demand the maintenance of the democratic traditions of the country rather than for-profit ends of a company (Eyfjörd et al., 1998, p. 496). Andersen (1998, p. 1993), from the University of California School of Medicine, questions the "opt-out" clause added to the bill during the revisions, although there has been still no mention of the informed consent to be obtained from individuals whose data will be included in the database targeting insurance companies as prospective buyers.

The proponents of the project highlighted the advantages of conducting such comprehensive research in Iceland as well as its contributions to the national economy. In this sense, a scientific project benefits from the setting in the country, providing a high quality of health care, detailed patient and genealogy records, and a well-educated public. According to Haraldsdodttir (1999, p. 498), then Deputy Permanent Secretary of the Ministry of Health and Social Security, despite ethical and legal concerns, the project gives Icelanders a unique opportunity to promote medical sciences because of its advantages to conduct population-based research and the dilemmas to preserve patient rights and the need for an informed public debate is recognized by the project.

There are also some points regarding the origin of the opponents of the project. For instance, Pálsson and Hardardottir claim that (2002, p. 280) many of the spokespersons for the Association of Icelanders for Ethics in Science and Medicine seem to see their scientific dominion as being threatened or devalued by deCode Genetics and the Biogenetic Project. Ragnarsson (1999, p.1354) claims that during the debates, some claims are based on false information. For instance, the argument that legislation allows a private company to link its medical records with genealogical and genetic data is false because personally identifiable data cannot be linked to encrypted medical data in the central database. The legislation simply forbids such use, and it is made impossible through encryption.

The updated version of the bill was finally enacted in December 1998, which was not sufficient to end controversy caused by the project Act on a Health Sector Database is considered the first legal regulation in the context of biobanking (Schneider, 2012, p.184). According to this legislation, the objective is to authorize the creation and operation of a centralized database of non-personally identifiable health data with the aim of increasing knowledge in order to improve health and health services. Within the context of the act, a health sector database will be established, which stands for a collection of data containing information on health and other related information, recorded in a standardized, systematic fashion on a single centralized database, intended for processing and as a source of information. The creation and operation of a health sector database are only permitted to those who have an operating license by the terms of this legislation. When an application has been received, the Minister of Health may grant an operating license to create and operate a health sector database subject to the further terms of this legislation. The licensee shall pay a fee for the grant of the license in order to meet the costs of preparing and issuing the license. The license will be for 12 years and will be renewable.

The wholly-owned subsidiary of deCODE Genetics, Islensk erfethagreining ehf., received a license permitting them to develop and operate the IHD in January 2000. DeCODE is to pay the Iceland government 70,000,000 Iceland krona (approximately $950,000 US dollars) per year, as well as 6% of pre-taxable profits. Following the HSD Act, a new institutional environment was created for the database as well. The Monitoring Committee of the Health Sector Database, the Interdisciplinary Ethics Committee, the Data Protection Commission, and the National Bioethics Committee are crucial elements of this new system. The Data Protection Commission was restructured in 2001 with a broader mandate following new legislation on personal data and privacy. The National Bioethics Committee was established in 1999. The main change introduced by the regulation was that committee members were no longer nominated by academic and medical institutions but by various Ministries and the Directorate of Health. In other words, as Árnason points (2007, p. 5), the power to nominate members of the Bioethics Committee was moved from academic and medical institutions to the executive branch of government.

The comprehensive database that deCODE planned includes medical records, genetic information, and genealogies, combining medical records with the other databases for scientific and commercial purposes (Pálsson, 2007, p. 96). In this setting, the healthcare data dating back to the early twentieth century will be collected through presumed consent, whereas participating physicians will take blood samples of the patients with informed consent. Additionally, through a software of Frisk Software, a contractor of deCODE Genetics, genealogical data, including family histories of the Icelandic population dating back to the ninth centuries, will be constructed called the Book of Icelanders (Pálsson & Hardardottir, 2002). Winickoff (2006, p. 82) claims that HSD Act's most controversial provision is the transfer of all medical record data to the licensee for commercial development without the express consent of individuals, by invoking a rule of the presumed consent. Stefansson and Gulcher further demand a mechanism which can be used for the cross-matching of medical information between the databases. Vigdis Stefansdottir, a Genetic Counsellor at Landspitali University Hospital who was interviewed in Iceland, sees a dynamic concept of informed consent as a solution to problems associated with the informed consent mechanism while conducting genetic studies:

> "Usually, when you are doing research with a large cohort when you may not able to say I am not quite sure this is the person, but you are making specific research on that person with her sample, I think dynamic consent is the way to go. If you have dynamic consent electronically, that is something online. When you are online each time, you have this cohort starting new research, and you inform participants online. You say this is the research and are you still willing to participate; this is the dynamic form of consent. I think this is the way to go. Many say it is complicated, but it is not" (Interview with Stefansdottir, 2019).

Indeed, according to the act (Article Eighteen), Icelanders would have six months from the construction of the database to opt-out unconditionally, which is quite problematic in terms of ethics and the protection of individual rights. According to Arnardottir et al. (1999, p. 353), although the Act is consistent with the European Economic Area competition rules, which are binding for Iceland as a member, due to the uniqueness of the project, commissioning one party to create and operate a centralized health sector database, a certain risk is taken. For Gottweis (2012, p. 215), fundamental debate took place concerning the ownership of and access to genetic information and medical records, since deCODE, as a private multinational company, would have the power to explore the genetic bases in the entire Icelandic population and to then profit from this research. Because of these concerns, by June 2003, roughly 20,000 people had opted out. However, the dimensions of the project which will combine the biological data and family histories of a whole nation, even if they will be all encrypted, to include ancestors who first settled in Iceland seem to more controversial, resembling the conditions of a dystopia. This is because a database that makes possible the total surveillance on genetic characteristics of a nation might cause eugenic policies to eliminate those who are susceptible to certain genetic conditions.

After the enactment of the HSD, the issue of democratically debating the draft bill was raised. The article written by the cofounders of deCODE Genetics, Gulcher, and Stefansson, relies on the quantitative aspect of the debate to prove its democratic feature on the ground that debate is one of the most important mechanisms by which complex ideas are processed by democratic societies. The controversy associated with the bill included 700 newspaper articles, more than 100 radio and television programs, and several town meetings all across Iceland, which according to the authors, provide each party with opportunities to explain themselves (Gulcher & Stefansson, 2000, p.1827). They also submitted the results of the polls that they organized themselves. For instance, on the eve of the parliamentary vote, a poll showed that 75 percent of Icelanders supported the passage of the bill, whereas 25 percent were against it. The database law was passed by the same margin, and since then, support for it has been growing. A poll taken by the Gallup organization at the beginning of April 2000 showed that 90 percent of those who took a stand on the issue supported the data-base law, and 10 percent were against it. In that way, the national media coverage functioned to propagandize the arguments of the project, therefore diffusing the discourses into the Icelandic society.

The arguments about broad media coverage that gives debate a democratic aspect have been affirmed by some articles, such as, Pálsson and Rabinow (1999) and Pálsson and Hardardóttir (2002). However, a media analysis of the debates about the Icelandic genome project conducted by Hjörleifsson et al. (2008) shows different perspectives than those of the proponents of the database. According to the study, positive media presentation of deCODE's research, initiation of new studies and cooperation with international industry or Icelandic and international institutions, enthusiasm and optimism about success for the company surpass the views stated by its critiques as the points of views of the opponents were not pursued by journalists and were in effect overshadowed (Hjörleifsson et al., pp. 383-385). deCODE's registration on the NASDAQ stock exchange in the US harmed Icelandic investors due to market speculation. However, the media coverage on Ríkisútvarpið (RÚV) on 18 July 2000, the Icelandic National Broadcasting Service, was in a different tone, exemplifying the national pride on the project.

> This is a very big day for the Icelandic financial sector and I would say for the entire national economy. . . . We are talking about tremendous amounts of money. . . . This will for example help

> correct our foreign trade balance. . . . We are now exporting services. . . intellectual capacity and . . . Icelandic knowledge, Icelandic information, Icelandic genes. (Hjörleifsson et al., p. 386)

The focus groups based research conducted by Traulsen et al. (2008), confirms the national solidarity of Icelanders on genomic research in the country and positive attitudes towards deCODE among laypeople instead of privacy concerns. As such, the economic expectations of Icelandic people and national values were articulated successfully with the achievements of the project in media coverage.

Individuals were encouraged to be active subjects of discourse of health, around genomic research and precision medicine, in Iceland through their participation into the Icelandic genome project. On the one hand, participation in research provides researchers with health data that they need to construct pedigrees of diseases and statistical correlations between the clinical data. This was affirmed as complying with the moral obligation. On the other hand, the active involvement to research subjects is affirmed as a norm or moral obligation by governing individual conducts. The research participation as a moral obligation is justified by some authors, for instance, Rhodes (2005, 15):

> “Since World War II, we have witnessed a dramatic increase in biomedical knowledge and tremendous progress in creating effective treatments for disease. These are benefits that flow from human subject research. We are also aware that we stand on the brink of a cascade of insights into human genetics and the promise of spectacular related advances in biomedical technology. Furthermore, we would want medicine to be able to provide effective treatment when we or our loved ones should need it. Without human subject research, those treatments are less likely to be available. So, in light of our appreciation of human vulnerability to injury and disease and our appreciation of the value of clinical research, reasonable people should endorse policies that make research participation a social duty.”

In this sense, biobank projects, including the Icelandic Genome Project, functions as the biopolitical regimes to govern individual conduct through research participation as active subjects of health discourse. This function is in parallel with self-rational patients who are expected to pursue their personal enhancements as the consumers of new health technologies.

Specific political settings result in the specific articulation of the local priorities to the settings of global economic projects such as genomic databases. Prainsack (2006, p. 232) points out, to understand a discursive creation of a particular risk setting, a particular understanding of risk with regard to genomics, and the microphysics of power inherent in them, we need to turn our attention towards politics. As Gottweis and Petersen (2008, p. 8) posit, in Iceland, like Israel, narratives of genes as national assets co-exist with privatizing tendencies in biobank development. In this sense, the global conjecture, the crisis in the local economy, and the ability of the project to articulate the national discourses were the factors that enabled the project to survive in spite of financial turbulence through stock share value of the company.

In the theoretical debates, there are analyses supporting the project in spite of contentious points regarding its ethics aspect, which dominated the discussions in parallel with the notion of individual autonomy. The opinions endorsing the project, in general, focus on the economic impacts of the project within the global conjecture. The controversial practices of the project are justified by the arguments on the ground that private and public hybrid model succeeds at the mobilizing sources effectively. For instance, Rabinow and Pálsson (2001, p. 171) claim that “without private initiatives, the potentially powerful resource represented by the synergies of combining medical, genetic and genealogical information would have been left unused. Although biopiracy is a very real threat in the modern world, fear of corporate power should not blind one to the possibilities of reconciling individualistic and collective enterprises” In this narrative, the hybrid mechanisms are affirmed as a truth regime in spite of the privacy concerns associated with human genetics research. Therefore, the countries with resources that are of economic value in terms of genomics are supposed to use them rather than waste it. Pálsson and Hardardóttir point out the increasing research capacity in the country and foreign investments as a result of the project. In this sense, the project created many new positions for scientists both within the company and at the University of Iceland. The company attracted much investment from abroad and created numerous jobs for Icelandic scientists, many of whom, in the absence of deCODE Genetics, would have been forced to seek employment abroad (Pálsson & Hardardóttir, 2002, p. 280).

Following the debates on the concerns about the Icelandic Health Sector Database, which was a product of a special law to construct a database, the project came to a halt because of a juridical action. The Icelandic Supreme Court ruled in favor of the plaintiff Ragnhildur Gudmundsdóttir who demanded her father´s name be put on the abstainers list held by the Directorate of Health in 2003. In this case, the Supreme Court decided that the Act on the HSD does not meet the requirements in the Icelandic constitution to provide adequate protection against the risk of the data being traced back to the relevant individuals for the purpose of protecting their privacy. In this way, the concerns about the privacy and the protection of personal data in the HSD, which was campaigned against by medical experts, was acknowledged by a juridical authority.

HSD was never set up but deCODE continued its research in Iceland regarding the genetics of common diseases. The company even started clinical trials on drugs after the decision of the Supreme Court. Although deCODE did reach many of the milestones of the agreement with Roche in 1998, it continued to co-operate with Roche in research and drug development. In these activities, the company still applied the data of the Icelandic population without a centralized database of health information (Árnason, 2007, p. 9). In the aftermath of the collapse of the database project, there has been neither specific research of deCODE on multiple sclerosis nor therapies developed through gene studies on the Icelandic people, although Stefansson's work with MS patients was used as a propaganda topic while attempting to mobilize public support for the public support for the project. Moreover, there has been no free medication given to Icelandic people, as promised during the Roche agreement.

The Supreme Court decision affected the stock performance of deCODE Genetics, which was floating around $2 and $3 per share, therefore worsened the financial capacity of the company. Following the global crisis in 2008, deCODE was not able to proceed with its operations further, first quitted the NASDAQ index, and then filed for bankruptcy. Holding the valuable genetic information of the Icelandic population, deCODE Genetics managed to find a new partner in 2012 and has been acquired by the US biotechnology giant Amgen, with a purchase value of $ 415 million. The company continues its operations as a fully-owned subsidiary of this company as the date of this thesis.

In the collapse of the project, the attitude of medical experts is crucial. Pálsson (2008, p. 42) claims that one of the main reason for the fall of the project is what he calls as biopolitics of the dispossessed which means the strategies of the resistance of the segments of the Icelandic medical establishment who feared the loss of their control and the security over medical practices in the country. The opponents of the HSD, who are mainly the physicians and academicians, organized under an association called Mannvernd (the Association of Icelanders for Ethics in Science and Medicine) in October 1999. It is not fair to describe these experts as reactionary forces that opposed the contributions of the project to the country, as well as revolutionary medicine, because their dominance in knowledge production was challenged. In a nation where NGOs are far from common, the emergence of Mannvernd was, in many ways, as significant a social and political event in Iceland as deCODE was, because this organization not only led the organized opposition to the HSD legislation but also initiated an education campaign to raise the level of public discussion about genomics and the project (Fortun, 2008, p. 19). This alternative way of knowledge production is probably one of the most prominent aspects of the Icelandic genome project. The large-scale genetic research projects and database attempts resulted in the unification and a monopoly in the knowledge production in parallel with existing discourses. In the name of the raising health literacy on genetics, these efforts are also being encouraged by international organizations campaigning for the application of genetic knowledge in public health as well.

3.3) Conclusion

In the Icelandic genome project, beyond the contradictory points regarding the consent mechanism and how the project was conducted, the commercial ends surpassed the public benefits. The collaboration of the Icelandic government with private enterprise set the conditions for a monopoly through a comprehensive regulation, which in turn exploited the public health data for-profit initiatives instead of supporting public health outcomes. The specific political-economic conditions in Iceland necessitating foreign investment after the collapse of the fishing industry and the competition state that was willing to invest in knowledge economies were the crucial factors for this comprehensive project. As a result, the establishment of a database to detect the genetic causes of complicated disorders for the benefit of public health in the name of a revolution in medicine and contribution to the local economy became policy targets that were not realized.

It is possible to observe the limited effect of the project on health care practices in the country. According to an interview with an Icelandic scholar (Interviewee 2), the unique aspect of genomic studies in Iceland was the cascade screening of the investigation of family members of the cancer patients performed electronically through computer technologies. Except that, the comprehensive scope of the genetic studies in the country has been conducted with traditional understanding in parallel with the practices in the other Western countries. The views of the interviewee on the conduct of the Icelandic genome project that

> "There are two major faults associated with the database. One fault is that there was no return on research regardless of how much information was relevant to participants. There was no mechanism to get out the information to the patients. The second one is the way the database was supposed to work. It was going to be protected by a monopoly. If there were no monopoly, then it would be considered to illegal to do things in this way. That is not how you apply monopoly. Let say the monopoly of transporting patients, or a transport company, transporting goods and services between City A and City B. That is a monopoly in which nobody else commercially transports. A monopoly never allows the monopoly to do things illegally if you do not have a monopoly. As a transport company, there will be no monopoly for driving faster than anyone else, driving faster than the speed limit, not stopping at red lights, etc. Part of the database is set up on that if we did not have a monopoly and someone else wants to similar things, there would be illegal." (Interviewee 2, Icelandic scholar, 2019).

deCODE succeeded in not only funding of the project through speculative stock-market transactions but also convincing Icelanders to support the project; in other words, not to opt-out from the database. The hybrid mechanism successfully articulated the nationalistic discourse with the project according to which it would contribute to the protection of the unique Icelandic genetic heritage. Even though the project collapsed and deCODE bankrupted during the financial crisis, the company managed to survive merging with a US biotechnology company because of the valuable genetic information that they owned. Beyond the misuse risk of the genetic information for commercial ends, a threat of the biopolitical control of individuals who consented to transfer their biological information to a comprehensive database for the benefit of the nation is a matter of fact.

CHAPTER FOUR-NEWFOUNDLAND AND LABRADOR

4.1) Overview

This chapter examines genetic research in Newfoundland and Labrador, and the province’s governance mechanisms in relation to public health practices. The focus of this section is the provincial approval model proposed as a governance alternative in the province. This model is developed by the province’s academic community and embraced by governmental institutions on the basis of the benefit-sharing principle. In this chapter, the private sector endeavors in genomics in the province, particularly Newfound Genomics, are also discussed. In order to analyze the emergence of investments into the genomics, this chapter will also explore the research context in Newfoundland and Labrador. The Baylor College of Medicine’s 1998 research project in Grand Falls, NL, occupies a central position because it affected the province’s subsequent research activities and policies. Specifically, the project was called Texas Vampires by local people, and it strengthened the rhetoric of the requirement for the involvement of local scientists in research projects. Finally, this chapter will also examine the NL Genome Project, an ongoing local research study led by the biotechnology company Sequence Bio, which represents the second wave of the private enterprises into the Newfoundland genome pool.

Newfoundland and Labrador has a long history of publicly funded genetic research driven by scientists based in the province. These activities date back to at least the 1980s (Rahman et al., 2003), while Pullman & Latus (2003) point out thirty years of research history in the province. Prior to increasing focus on genomic studies together with the HGP, scientists from the Memorial University of Newfoundland were the leading players of the research into genetic roots of diseases with high prevalence in the province. It was also a period in which local researchers collaborated with the scientific community both at the national and international levels because genomic studies in the province were limited. For example, researchers at Memorial University worked with John Hopkins University to detect a gene responsible for specific colon cancers and with McGill University to work on a gene linked with a form of hereditary ataxia. These events exemplify partnerships with outsider researchers. These projects exemplified well-functioning cases of scientific alliances to conduct research on local communities in the *Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador Report* (2003, pp. 10-11). The involvement of local researchers was a decisive factor that gave legitimacy to the research projects and proclaimed as a prerequisite by academia and provincial government, for both the scientific success of the projects and the protection of communities targeted by that research.

The scientific motive behind the interest in the province, like in Iceland, relies primarily on the argument that genetically homogenous populations serve for ideal sets to conduct genetic research to detect the roots of the diseases because of the high prevalence of genetic disorders. These disorders are often linked with the existence of the founder effect, which is the establishment of a new population by a few original founders resulting in minimal genetic variation (Diamond & Rotter, 1987, p. 105). The population of Newfoundland that descended primarily from European immigration from Southeastern Ireland and Southwestern England is prone to certain monogenic diseases because of the founder effect and inbreeding factor (Zhai et al., 2016, p. 1068). The incidence of the Bardet-Biedl Syndrome (BBS), a rare genetic disorder in the province, is ten times that of white people of northern European ancestry because of the founder effect and subsequent isolation (Young et al., 1999, p. 1680). The presence of genetic disorders frequently is also the reason for the establishment of medical units to study these conditions in the province. According to the Newfoundland and Labrador Medical Association, the province itself established a Medical Genetics Program in 1986 because of certain genetic disorders

4.2) The Emergence of research activities in the province

The first private-sector enterprise for genomic research in the province is the Newfound Genomics. This company was established in 2000 as a joint venture of British biotechnology company Gemini and a small NL company, Lineage Biomedical. The year in which the company was established marked a rush for genome sequencing following the Human Genome Project (HGP). In this sense, this joint-venture company with a local partner reflects the endeavors in search of new sites for research following the path of the HGP.

In the period following the launch of the HGP, there is also an increase in the scientific publications about the populations promising advantageous settings for genetic research, including Newfoundland. For instance, in a collaborative article led by the researchers at the Memorial University, the population of the province was described as one that had explicit advantages for genetic studies as compared to less homogenous populations, as well as to similarly isolated populations (Rahman et al., 2003). During that period, it is also possible to observe the revival in scientific studies with similar themes, such as (Zhai et al., 2016), during the second wave of private enterprises represented by Sequence Bio into the Newfoundland gene pool.

The province attracted the interest of national and international media in the onset of genomic age, which was triggered by the HGP, and private enterprise to sequence genome in the province. The media coverage of genetic research was a crucial point to both encourage investment into the sector and also to increase the market value of specific projects already invested. The Guardian article by Meek in

2000 is an example of interest in genetics. This article makes an explicit comparison of the Icelandic Genome and overseas investments of British company Gemini into Newfoundland’s gene pool through Newfound Genomics. Being aware of the controversial aspects of the project in Iceland regarding patient confidentiality and ownership of human genes, Meek (2000) emphasizes the difference between Newfound Genomics and its Icelandic counterpart. In this article, Gemini's clinical director and vice president, Howard Christley’s statement, describing the population of the province as the “inbred population“ was also underlined. Atkinson’s article in the Globe and Mail in the same year also includes a comparison between Iceland and Newfoundland. The author depicts the gene pool of the Newfoundland as a priceless commodity and predicts that the province can benefit from its genetic legacy (Atkinson, 2000). In the article, the arguments of Dr. William Davidson[8] are cited, who is in favor of an alliance with a cash-rich pharmaceutical giant in parallel with Iceland.

The salience of the genetic pool of the province and investments into this source got media coverage with slightly different tones. For instance, in a more critical account of the developments in the province, Staples (2000) in the Globe and Mail discusses the inadequacy of framework concerning the use of medical data in research activities. Taubes (2001) in MIT Technology Review, examines the strategies of Newfound Genomics as a venture investment in which the target was summarized as to develop an international hub of clinical genetics for the benefit of the province and the patients around the world suffering from the diseases that company tried to detect its genetic roots. In the media coverage of the Newfoundland case, the comparison with Iceland is the most characteristic feature of the publications by attempting to make the province

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[8] Davidson was the Dean of Science at Simon Fraser University at the time. Before this position, he led research on BBS in the province as a microbiologist at Memorial University.

more known in the international area and illustrate it as a new model and site which has similar characteristics with Iceland in terms of genetic legacy but differs from its contradictory way of processing genetic data.

Among the increasing attention to the province, Newfound Genomics was established as a joint venture of Gemini Genomics plc, a biotechnology company based in Cambridge, the UK, and Lineage Biomedicals Inc., based in St. John's Newfoundland and established by local physicians. According to the United States Securities and Exchange Commission (SEC) data filed in 2000 as a NASDAQ listed-corporation, Gemini Genomics, operates in the fields of clinical genomics to identify the relationships between human genes and human health and disease since its establishment in 1995. The founder and chairman of the company was Michael Fitzgerald, who was a barrister specialized in the provision of international banking and corporate legal services. Lineage Biomedicals, the local partner of the joint venture, is led by Dr. Wayne Gulliver, who works as a dermatologist in St. John's. As a Newfoundlander, Dr. Gulliver, who studied medicine at Memorial University, worked on psoriasis, which has a high prevalence in the province.

Gulliver had experience of collaborating with outside researchers before the Newfound Genomics. He participated in previous genetic research conducted by a California based biotechnology company Celltech about this disease by collecting samples in the province (Pullman & Latus, 2003, p. 549). Taubes (2001) states that Gulliver met Paul Kelly, CEO of Gemini Genomics, which had already assembled a huge international network of twins to use in searching for gene-disease associations, and convinced him to extend the company's network to include the unique gene pool of the province. It looks like this joint venture was also in parallel with the strategy of Gemini Genomics. As indicated in their company filing to the SEC, the company increased its collection of clinical samples and its ability to access further clinical data through its acquisition of Eurona in December 1999. Based in Sweden, Eurona provided Gemini Genomics with access to several million tissue samples and genetic materials from volunteers affected by a range of diseases because of clinical collaborations with university and medical institutions that they had made before the acquisition. In this sense, the partnership with a local company which was also led by reputable physicians in the province was an appropriate strategy both to satisfy the expectation for the involvement of local people and also to enrich the clinical data considering the fact that Gemini Genomics was founded and chaired by an entrepreneur investing in the promising sectors.

The company then started its preparations to conduct genome research for specific diseases in the province by recruiting local scientists and projecting its facilities. In this context, Dr. Proton Rahman, professor at Memorial University, was appointed as a chief scientific officer to manage sample collection processes. Another significant person in the province Siobhan Coady, a successful entrepreneur and current Minister of Natural Resources of the province was named as the CEO of the company who held this position until she entered the politics in 2008. With regard to investments into facilities, Newfound Genomics purchased a freehold property in St. John's, Newfoundland. This property was designed to be used to provide facilities for sample collection, office space, and laboratory facilities for the company's operations (United States Securities and Exchange Commission Form Annual and transition report of foreign private issuers, 2001, May 23). In February 2001, Gemini Genomics acquired the outstanding share capital it did not then own from Lineage Biomedical Can for $60,000. This amount was recorded as goodwill since the joint-venture had no identifiable assets. The company was well received in the province thanks to its commitments to the benefit-sharing model and contributions to the funding of research facilities at Memorial University, such as the purchase of gene sequencer for the university, as stated in the news release of Industry, Trade, and Rural Development in 2001. However, another development in 2001 seems to affect negatively the funding possibilities of the company, which is the acquisition of Gemini Genomics by Sequenom of San Diego, California. After this merger, Newfound Genomics had to continue its operations, a single company depending primarily on government support. Although the company managed to get support from governmental agencies and academia, without adequate funding or opportunities for speculative stock-market transactions, like in Iceland, it is highly unlikely to accomplish the genomic research.

During the recommendation for the provincial approval model and the formation of legislative framework associated with it, Newfound Genomics was in a close relationship with Memorial University and the provincial government. As an example of academic collaborations, the company, while doing research for developing a pharmacogenetic diagnostic test to predict drug response in patients partnered with the Population Therapeutics Research Group (PTRG), a non-profit research team led by Dr. Rahman in the Faculty of Medicine at Memorial University in 2006. The company collaborated with the Genesis Group, the technology commercialization arm of Memorial University, to pursue a program of collaborative research and to bring the potential pipeline of promising discoveries to the market in 2008. In this context, the company committed to developing a diagnostic genetic test for arrhythmogenic right ventricular cardiomyopathy, a deadly genetic heart condition highly prevalent in the province called as “Newfoundland curse” killing young people without any prior symptoms, whereas researchers at Memorial University worked on the discovery of the gene responsible. In its partnership with the provincial government, the company represented the province in reputable technology conferences, such as BIO 2002 in Toronto, an international biotechnology convention and trade exhibition. Whereas the delegation for the event was organized by Bio-East, the Newfoundland and Labrador Bio-Technology Network, and The Department of Industry, George Sweeney, Parliamentary Secretary to the Minister of Industry, Trade, and Rural Development for Information and Advanced Technologies and Dwayne Goudie, Managing Director of Bio-East made statements about the strategic growth opportunities in biotechnology as knowledge-based industries and government's commitment for expanding the biotechnology base (Government of Newfoundland and Labrador, Industry, Trade and Rural Development, News Releases, June 07, 2002). The company also took part in the Boston Trade Mission as a member of Team Canada Atlantic, which is a partnership of ACOA, Agriculture and Agri-Food Canada, Industry Canada, Foreign Affairs and International Trade Canada, Enterprise Cape Breton Corporation and the four Atlantic Provinces. The provincial government supported the company as an enterprise in the high-technology sector, increasing the competitiveness of the province in the knowledge economies model just as the provincial approval model as a legislative framework did.

The provincial government supported who wanted to benefit from the influx of capital investment into local economy Newfound Genomics in different ways. The company was also awarded the St. John's Board of Trade Business Achievement Award, a reputable accomplishment granted in the mandate of Innovation, Trade, and Rural Development (The Department of Innovation, Trade and Rural Development, Annual Report, 2007). The company got direct financial funding from the provincial government during the economic crisis period. NewLab Clinical Research, a group company, received a $ 500.000 investment from the Department of Innovation, Trade and Rural Development within the commercialization program, whereas Newfound Genomics got another $ 500.000 in 2008 from the same program (Office of the Auditor General Newfoundland and Labrador, 26 January 2011). However, these financial supports were unable to save the company, which, following the financial crisis ceased its operations in 2011. Additionally, the same year an investigation by the Auditor General regarding the funding to two group companies detected several issues on these transactions, such as, the owner of two medical research entities did not contribute any of the required $855,000 equity contributions, the Department did not complete proper due diligence relating to the approval and assessment process, disbursement of funding and monitoring, e.g., contrary to Treasury Board policy, cross-departmental checking for amounts owing to Government was not fully completed; documentation was not adequate to support any of the $5.2 million in estimated project costs.

4.3) Provincial approval model and the regulation of research in the province

Increasing interest in genomics both as a burgeoning field of science promising a revolution in medicine and also as a high-technology to invest in for quick returns makes the province attractive for gene hunters. The activities of outside researchers as a result of increasing interest in genomic studies, mainly the infamous works of Baylor University in the province, who did not coordinate with local counterparts, have led to concerns (Pullman, 2005). These challenges from outside call attention to the necessity for the governance of genomic research, or at least appropriate legislative action, instead of seeing the involvement of local researchers into genetic studies as a balance factor. The challenges were not merely caused by the commercially driven genetic research in the province. As was the case in the works of the University of Western Ontario, in which outside researchers came to the province to investigate a disease associated with HLD cholesterol whereas local scientists were unaware of the project until a newspaper headline criticizing the dietary habits of the Newfoundlanders (Pullman & Latus, 2003, pp. 547-548). The fact that the direct intervention of outsiders was regarded as a threat constitutes the foundation of the model proposed by local scientists and adopted by the provincial government thereafter as there was no regulation to regulate research on human genetics in the province.

In the efforts to develop governance mechanisms, the provincial government called on expert knowledge. Dr. Verna Skanes, retired Assistant Dean of Research and Graduate Studies at the Faculty of Medicine at Memorial University and a member of the Standing Committee on Ethics of the Medical Research Council of Canada, was selected to prepare a report about issues associated with human genetic research (Government of Newfoundland and Labrador, News Releases, May 2, 2000). The commercialization of human genetic research, which was conducted by outside researchers investigating the DNA of Newfoundland families without informing them about the research results on the contrary to ethical guidelines applicable, was pointed out as the factor to ask for expert knowledge. In the report, issues such as research ethics, legal protection for the research participants, informed consent, and privacy and confidentiality, as well as the establishment of a provincial research ethics board were discussed. Additionally, the Ministry of Health and Community Services, as per this news release issued the Honourable by Roger Grimes, projected to set policy and standards for genetic research reviewing the genetic research policies around Canada and the world, particularly mentioning Iceland as a case. As can be seen in this new release, the issues addressed in the report bear the perspective of governance mode based on the provincial ethics board in that the level of genetic research targeting the province goes beyond one that can be dealt with the involvement of local scientists.

Initially, the governmental agencies focused on the commercialization of genetic research to be addressed in a report by an expert in the field (Pullman, 2005). In this sense, academic research, which is to be conducted by outside researchers and limited with public health ends, will be excluded. According to Botting (2001, pp. 73-74), public health authorities had concerns about the activities of recently-established Newfound Genomics, and Dr.Skanes points out that the ethical and legal framework composed of Tri-Council Policy Statement for Research Involving Human Subjects are not sufficient to regulate the genetic research that has facilities to investigate the complex genetic disorders because of the biotechnological developments in parallel with the HGP. However, the recommendation for an ethical board in the report seems to represent a change of the perspective from a limited concept of the alleviation of the side impacts of commercialization to an authority granting the legitimacy to the research proposed. For Pullman (2005, p. 76), Skanes broadened the content of the report; as a result of her consultations during the preparation period, thus emphasizing the need for the "legislative oversight "of all health research regardless of the purpose. The framework for a provincial ethics board projected in the following policy recommendations is grounded on this ethico-legal concept of the legitimacy of genetic research.

A novel concept of a benefit-sharing model, which was declared by the ethics committee of Human Genome Organization, a prominent international non-profit organization regarding genomic studies, is of significant impact on the genomic governance model in the province. The promotion of the model in 2000 coincides with the developments in the same year in the province affecting the future path of genomics locally, the establishment of Newfound Genomics in February 2000, and the Skanes report in May 2000. The benefit-sharing comes to salience because of the increasing share of private sector investments on genetic research according to the organization. The HUGO Ethics Committee Statement (2000a, p. 366) recommends that “in the case of profit-making, the general distribution of benefits should be the donation of a percentage of the net profits (after taxes) to the health care infrastructure or for vaccines, tests, drugs, and treatments, or, to local, national and international humanitarian efforts.” The emergence of the private sector genetic research in Newfoundland and policy recommendations of the local academic community with regard to the governance of these activities comply with the statement of the committee. Another publication (2000b, p. 49) of the Committee particularly endorses Newfound Genomics, which devotes 1% of net profits to a charitable trust for the general population. In addition to this, the emphasis on communitarian rhetoric to “ascertain community value and needs” and “ build greater trust and reciprocity with participants” as outlined by Knoppers (2000, p. 214), then chair of HUGO Ethics Committee, increased the popularity of benefit-sharing among academia in the province, which is frequently compared with Iceland. In this sense, communitarian influence on ethical debates is not only limited with the community values but also includes “collective intellectual property and the socially embedded nature of the human individual will”(Pálsson & Rabinow, 167,2001). In benefit-sharing model, the influence of communitarian perspective goes beyond the affiliation with the community values and property rights on human genes, extending into assuring distributive justice of benefits created through genetic research.

On the policy side, the ethics board and related regulations continue to be discussed following recommendations for the legislative action. In 2003, a project team, the members of which were affiliated with Memorial University except for a lawyer from a private law firm in St. John’s, prepared the Policy Implications of

Commercial Human Genetic Research in Newfoundland and Labrador Report for the Newfoundland and Labrador Department of Health and Community Services. This report authored by Associate Professor of Medical Ethics Darryl Pullman and a post-doctoral research fellow Andrew Latus, recommend the establishment of a Provincial Approval Model which requires the benefit-sharing proposals as well as ethics approval to conduct genetic research in the province. While locating benefit-sharing centrally in the model, the report also recommends the creation of a Health Research Ethics Board (PHREB) and a Standing Committee on Human Genetic Research (SCHGR). According to the report, the genetic research proposal in Newfoundland and Labrador should obtain the approval not only from the PHREB but also from the SCHGR by submitting a proposal for benefit-sharing to the latter one. In this model, a committee composed of experts appointed by Minister of Health and Community Services, the President of Memorial University, and the Minister of Industry, Trade, and Rural Development will decide on the potential benefits of the research into communities in the province, ensuring the legitimacy of the proposals. According to the report, the implementation of the model will make the province a leader regarding the regulation of human genetic research, increasing the competitiveness of the province in parallel with the strategies on the investments into knowledge economies.

In the Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador Report (2003, pp. 4-6), the ethical challenges were regarding research on human genetic were addressed to present a model which would comply with the ethical principles, as well as legal and social norms. These challenges consist of the legal status of human DNA, the ownership of it, privacy and protection concerns associated with genetic information, human dignity and new intervention techniques through genetics. Informed consent mechanism and disclosure of research results with research subjects are ethical standards to address the challenges, the violation of which breaches serious cases of victimization. Research activities, like Texas Vampires case, in which health research ethics on the consent mechanism and the disclosure of research results were violated, bear the risk of victimization of research participants in the expectation of the remedy for the disease. In this sense, the report prepared by Pullman and Latus addresses the ethical challenges that stem from universal principles regarding research ethics and the precautions to regulate health research in the province to protect local people form the risk of victimization.

The particular cases in the history of genetic research illustrate how the breach of ethical principles, most notably, the informed consent mechanism and the disclosure of research results with participants result in the victimization. As was the case in the story of Henrietta Lacks, an African America woman, whom tissue samples passed to researchers without her consent during the medical procedures were at the Johns Hopkins Hospital for cervical cancer in the 1950s and grown outside body by researchers after her death (Beskow, 2016). Whereas the HeLa cell in vitro cultivated from Lacks' tissue samples were not patented, in the case of John Moore, the cells collected from the leukemia patient Moore's spleen at the University of California, Los Angeles (UCLA) were used to develop a cancer drug. The discovery was patented by the Regents of the University, naming it Mo cell, although Moore had consented and received no economic benefits. Moore's lawsuit to benefit from the patent was denied by the Supreme Court, but it sparked debates on the role of property rights and the human body and parts. According to Wald (2005, 221), Moore's case also sheds light on the biocolonialism in that an unempowered white man turned into a position which was open for the exploitation just as indigenous people suffered from DNA research targeting them for a long time. These particular cases illustrate how the racialized and gendered impacts of genomic research and the requirements of the ethical standards to regulate these research activities as outlined in the Policy Implications of Commercial Human Genetic Research (2003).

The provincial approval model developed by the Newfoundland project team, mainly by Pullman and Latus, influenced not only the legislative framework concerning the provincial ethics board but also was discussed at the international level as a policy and governance alternative for genomics. The Scottish scholars Gill Haddow, Graeme Laurie, Sarah Cunningham-Burley, and Kathryn Hunter affiliated with the University of Edinburg elaborated on the Newfoundland model in their collaborative work. According to the authors (2007, p.279), the provincial approval model based on a benefit-sharing proposal reviewed by the provincial board deserves to be endorsed in that this model takes three principles into consideration, which are distributive justice, respecting the communal nature of the information contained in DNA, and public administration and promotion of health as a common public good. The community-focused approach about the beneficiaries of the benefits, comprehensive account of benefit to include community’s interest in health and wealth benefits in the model, convinces the authors to accept benefit-sharing as responsibility of both researchers and private enterprises as part of the entire governance framework (Haddow et al., 2007, p. 280).

The Newfoundland model and its endorsement during the Generation Scotland, the Scottish biobank debate received several responses. This database projects to construct a database with family histories of the common diseases in Scotland. During the concerns about the commercialization of genetic research Haddow et al. (2007) proposed a model of benefit-sharing. Reardon (2017, p. 106) criticizes this model developed, in parallel with the benefit-sharing model the authors endorsed in that it projects a simple understanding of benefit limited to the share of the profit which needs to be more inclusive regarding the definition of benefit. Elger (2016, pp. 248-49) questions the possibility of an international committee specialized in benefit-sharing instead of what is modeled in Newfoundland as a provincial one to serve for national ethics committees. The author also questions the potential side effect of benefit sharing on the condition that model would create an incentive for economically disadvantaged persons encouraged to participate in research. Winickoff claims (2008, p. 9) that in the Newfoundland model individuals or collective groups are not able to control the choices about biovalue creation, in that the model gives the authority for the allocation of collective goods through biobanks to the expert decision-makers, to avoid ~~of~~ potentially conflicting goals, e.g., between building local economic value and advancing global research access. These academic discussions about the reception of the provincial approval model highlight the different aspects of the model, such as regulatory basis and its impact on economic development. In addition, the benefit-sharing model, in general, accepts the distribution of benefits as a basis. In this sense, the model shifts the emphasis from dialogue to exchange or distribution" (Hayden, 2007, p. 732). In the last instance, the concept of legitimacy in a juridical sense, aiming to end of distributive justice based on the decisions of experts, which is capable of making a judgment on the benefits for the community according to the community values, represents a strict biopolitical regime ignoring the individual demands and intrasubject relations.

The recommended legislative framework, in association with the provincial approval model, was implemented in the province in 2011. The Personal Health Information Act (PHIA) came into force on April 1st, 2011, the Health Research Ethics Authority Act, and the Health Research Ethics Authority (HREA) of Newfoundland & Labrador came into effect on July 1, 2011, serve for the intended framework during a decade long preparation period. PHIA regulates the methods for the collection, use and disclosure of personal health information to protect the confidentiality of that information and the privacy of individuals, mechanisms that govern individual access to personal health information, and responsibilities of the persons/institutions who act as custodians of personal health information. Whereas PHIA includes provisions regarding the privacy of personal health information and mechanisms and responsibilities for custodians to protect individuals from the disclosure of their confidential information, the research that obtains approval from a research ethics board under the Health Research Ethics Authority Act is exempted from the obligations on the disclosure of the personal health information. According to the article (2012, p. 40), authored by Patricia Kosseim from the Office of the Privacy Commissioner of Canada and academicians from the Faculty of Medicine and Population Therapeutics Research Group at Memorial University, including Daryl Pullman, "the unique legislation creates a province-wide research ethics authority to ensure that all human health research is reviewed within the province and conducted ethically" Kosseim et al. (2012, p.40) also added "HREA is the first legislative scheme in Canada that incorporates the TCPS thereby elevating its status from national guidelines into law. Interestingly, however, HREA also provides for the possibility that the REB may, with the approval of the HREA, vary a standard or rule contained in the TCPS where the board considers it appropriate to do so." Although there is no specific board established to review benefit-sharing approval, the authorities appointed (to the provincial ethics boards which administer exemption of personal health information disclosure for research approved by an ethics authority and flexibility of the board to employ while reviewing the proposals along with TCPS seems to have satisfied the academicians who prepared the report for provincial approval model.

There is an ongoing private sector-driven scientific project called Newfoundland Genome Project, launched in August 2019, which is the one that medical ethicists, including Daryl Pullman, approached with caution. The project is being conducted by Sequence Bio, which is a St. John's based company founded in 2013. Of the co-founders, Chris Gardner is the CEO of the company since 2016, when former CEO Tyler Wish resigned. Gardner, a native of the province, studied Business at Memorial University while the former CEO, Wish, received his Ph.D. in medicine from Memorial University and is currently in cannabis business with his new company NACBio in Vancouver, BC.

The company was invested by the provincial government through share purchase valued at $300.000 in 2015 by Venture Newfoundland and Labrador, a venture capital fund established by the provincial government and managed by Pelorus Venture Capital Ltd. to support innovative entrepreneurs with high-growth potential start-ups. Concerning the support of the provincial government to the start-up company, Darin King, Minister of Business, Tourism, Culture, and Rural Development, stated that (Government of Newfoundland and Labrador, News Releases, July 21, 2015):

> "government established Venture Newfoundland and Labrador to support entrepreneurs and to encourage innovation and new business growth. Investments such as this are essential to fostering a more diverse economy and are a key factor in this government's Population Growth Strategy. I am pleased to celebrate today the first company to benefit from the fund, Sequence Bio".

In addition, Sequence Bio and provincial government, during the administration of Health and Community Services Minister Steve Kent in 2015, signed an agreement for looking for 100,000 people to capture genomic and phenotypic information. The agreement also had a partnership with Genospace, a company based in the USA. The company managed to strengthen its financial position through venture capital funding. According to an article in The Independent, the company attracted more than $4 million investment from venture capitalist firms following the agreement with the provincial government in 2015 (Baird, 2020).

However, the Health Research Ethics Board (HREB) did not approve the proposal of the company despite governmental support. The company took HREB's decision to the Supreme Court of Newfoundland and Labrador and, after the resolution of the Supreme Court, managed to obtain approval of HREB for the first phase of the project in 2019 with a limited number of participants. NL Genome Project is being conducted with the collaboration of family physicians, nine as of the date of the thesis. In this project, the saliva samples of the participants are collected with informed consent. The project promises to create over 100 new jobs and invest $150 million in the provincial economy. The company conducts the project in collaboration with the provincial government, as well as Memorial University, through a Master Licensing Agreement, according to which the University will be compensated for discoveries made using any of their existing data. According to Baird (2020), the company finds a solution to access the data of the Newfoundland Labrador Centre for Health Information, which maintains health databases in the province, as this institution refused their data access request.

The company has developed close connections with politicians to secure its position as well. For instance, Sequence Bio, according to the website of the company, worked with former Senator Jim Cowan to support the passage of Bill S201 enacted in 2017 to ban genetic discrimination, which can be used against people with genetic dispositions for certain diseases within the context of health insurance policy coverages. Another prominent figure of the province Andrew Furey, who at the time of writing, is campaigning for the leadership of the Liberal Party of Newfoundland and Labrador and has been a board member of the company. The case of Sequence Bio proves the salience of the research ethics board, which were able to reject the research proposal of the company and delayed the economic returns of investments into the company, in the governance of genetic research as projected by the provincial approval model, despite the collaboration of the company with the provincial government and venture capital investments. However, the Sequence Bio case tends to approach a hybrid governance model because of the partnerships with the provincial government, including direct investment into the company, and relations with local politicians.

4.4) Conclusion

The development of the genetic governance mechanisms in the province complies with neoliberal policies to channel the local values into the market mechanism, including the genetic legacy of the population, thereby creating high-technology sectors for competitiveness. Meanwhile, the governance model called ‘provincial approval’ bears strong characteristics of communitarianism. In the benefit-sharing principle, the community plays a crucial role, as well as expert knowledge, to achieve the distributive justice of benefits among community members.

However, it is complicated to implement benefit sharing principle in genomic research. There are crucial points to define, including the content of basic principles. Ten Have (2011, pp. 320-321) mentions two problems that need clarification for the application of benefit-sharing. The first one is related to the boundaries of one of the fundamental concepts, the definition of community in this new global bioethics discourse. The second problem is that there are different conceptions of property. In the policy-making processes, it is essential to define these concepts clearly to authorize the experts for the application of benefit-sharing into practice.

The policymakers in the province applied to expert knowledge because of the technical nature of the issue. It is quite usual that the assistance of scientists would be called upon for a subject like genomics. However, what is unique in the Newfoundland context is the anticipated role of these experts. In the provincial approval model, experts are allowed to decide on the conformity of research proposals with the community values and distributive justice principles. In this setting, the functions assigned to experts in the ethics board to ensure the distributive justice of benefits accrued through genetic research go well beyond the meaning of the community and the provincial government as well, thereby resulting in an institutionalized legitimacy by expert knowledge.

The communitarian perspectives focus on community values and the role of institutions on the individuals, in other words, in the subjectification processes. Walzer (1984, pp. 328-329) claims that institutional discipline, through the work of internal elites, professionals with claims to scientific knowledge, is exaggerated by Foucault. In this framework, the success of these elites, and their ability to sustain their discipline without state power is quite limited. If the focus of communitarian critiques on neoliberal policies were on the homogenizing impact of those policies on individuals as a tool of uncoercive oppression, their arguments and the models influenced by them would be much more helpful. However, they affirm institutions that discipline individuals to create docile bodies, as Foucault pointed out, it seems to ignore the subjectification processes and power relations for the sake of the shared values of the community. It is not a logical conclusion that a community can cure its own diseases within it through attachment to community values. Ignoring the disciplinary functions of the institutions creates an inadequate analysis, just as the ones that rely on the individual autonomy principle ignoring the conduct of conduct.

CHAPTER FIVE: CONCLUSION

5.1) Overview

This chapter will summarize how genomic governance mechanisms are shaped by political and economic factors, and function to create alternative discourses based on cases illustrated in previous chapters. In parallel with the political-economic transformation of welfare states under neoliberalism, changes at the governmental level also appeared. This is the “emergence of a range of rationalities and techniques through regulated choices made by discrete and autonomous actors” (Rose, 1996, p. 328). New techniques of governance aim to link personal conduct with socio-political objectives at the macro level creating regulated freedom for subjects (Miller & Rose, 1993). In this sense, “‘biopolitics’’ signifies from the start a conceptual complexity that is in keeping with real tensions between the simultaneous promotion of individual freedom and the justification of coercive strategies in liberal societies” (Raman & Tutton, 2010, p. 716). Whereas emphasizing the autonomous -rational subject, a new mode of governance also creates alternative discourses that coexist with governmental techniques to convince individuals that they pursue their interests as well.

The neoliberal model reshaped public services towards the targets of privatization and marketization. The transformations in the delivery of public services led to alterations in the rationality and practices of governance. ”As an assemblage of governmental practices, public health not only through state-directed regulatory strategies but also by invoking individuals’ desires to regulate their own conduct in the name of health“ (Polzer, 2005, p. 80). In this setting, the notion of patient empowerment functions to canalize the conduct of individuals in parallel with the targets of a privatized health care system while convincing them they are pursuing their choices. Entrepreneurial individuals, making decisions based on the risk and opportunity, are the key elements of new techniques of health promotion focusing on the preventive measures (Petersen, 1996). This understanding of health promotion addressing self-rationality and self-regulation is in parallel with the controlled freedom of subjects under neoliberalism. Empowered subjects live this environment of freedom as consumers of genetics-based diagnostic products and personalized therapies. “Patients actively engage with the production, interpretation, and enactment of health data and involve in clinical decision-making through digital health technologies as well” (Petrakakia et al., 2018, p. 150). The freedom of subjects through the entrepreneur-consumer role is also strengthened with opportunities because of the increasing health technologies market. Individuals can invest in biotechnology and pharmaceutical companies that discover new diagnostic and therapeutic products to render medicine more precise, therefore shaping the policy-making in this field. Even the function of expertise changed under the neoliberal shift. “The authority of expertise detached from the apparatuses of political rule is relocated within a market governed by the rationalities of competition, accountability and consumer demand” (Rose, 1993, p. 285). The privatization and marketization of public services under the neoliberal model create a discourse based on the dominance of the free market as a regulatory basis of activities, therefore encouraging consumer-entrepreneurship and academy-industry collaborations.

In brief, biotechnology companies, venture capital investors, and governments play significant roles in the emergence and support of biotech industry, including genomic research activities and biobanks. Discourses of rational self-interest and personal responsibility are deployed by those parties; in particular cases, national identity and ethnic pride are also articulated with the emphasis on the rational self in parallel with neoliberal governance model. These discourses mask not only ethical concerns but also power relations between the parties.

5.2) Evaluation of Case Studies

The cases examined in the previous chapters have been highly influential in the discussion about the governance of genomics. Issues of presumed consent and executive rights of a private company to the comprehensive database, which includes not only the genetic profiles of the current population but also links ten generations of Icelanders, have been discussed worldwide even after the debates on HSD as well. According to Andorno (2016, pp. 29-30), the Icelandic database is not compatible with European Directive 95/46, which regulates data protection on the basis of informed consent for personally identifiable information and the World Medical Association critiques Iceland in its declarations in 2002 as well.

The Icelandic experience also provides lessons to other countries attempting to construct similar databases. ”The difficulties in developing the Iceland biobank probably prompted the UK Biobank’s extensive efforts to connect social groups and civil society organizations with the biobank” (Gottweis & Lauss, 2012, p. 70). “Proponents have emphasized the open and democratic nature of the project – voluntary participation, feedback and communication – and its commitment to the public good. There is an evident attempt to distance the project from the Icelandic Health Sector Database that was the focus of much critical attention and to help dispel any concerns that people might have about coercion, commercial profiteering and the improper use of information “ (Petersen, 2005, p. 286). For Rose (2001, p. 123), in addition to scientific-academic debates, global players in the pharmaceutical industry, such as Smith Kline Beecham (GlaxoSmithKline), developed more cautious approaches emphasizing hybrid structures between the state and the market and need to work slowly and consensually to include all parties, contrary to the market-driven approach of the Icelandic case.

The benefit-sharing provincial approval model developed for Newfoundland and Labrador was echoed during the debates for the Scottish Biobank. Haddow et al. (2007, p. 279) endorse this model, which they claim is “applicable to other contexts of benefit-sharing, although designed to take account of the specific historical–political-economic circumstances of Newfoundland and Labrador.” As can be seen, both cases aforementioned have specific implications on the debates of the governance of genetic research. The salience of these places goes beyond being homogenous populations, which is advantageous to research the genetic roots of the diseases in that the practices and theoretical perspectives to govern the research activities encompass the particular responses of the parties involved and political-economic factors.

Economic advantages to local economies through investments into the genetic pool of Iceland and Newfoundland are the main factor that motivates actors residing in these places. In fact, both of the cases were “quasi-peripheral populations” within the global core when new genetics came into prominence globally in the late 1990s. The geographic isolation and the economic crises of local economies, which were hit hard by the decrease in the fishery sector in the North Atlantic, were the main factors rendering new economic development strategies more attractive in both cases. In this sense, the contribution to local economies played a crucial role in recognition of genetic endeavors in these regions. For instance, the “Icelandic project emphasizes the opportunities of medical advances, work, entrepreneurship, and private initiative, in the age of the challenging new economy and stagnant or declining fishing stocks “(Gottweis & Zatloukal, 2007, p. 209). There were direct referrals to the benefits of the genomic projects to the economy in the Newfoundland case as well. As outlined in

“Policy implications of commercial human genetic research in Newfoundland and Labrador“ (2003, p. 3), infrastructure could be developed, the province is research-capacity enhanced, and the provincial economy is stimulated as a result of genetic research conducted in the province. These promises not only addressed what states are searching for, maintaining their national competitiveness under the neoliberal model and knowledge-based economy. At the individual level, economic benefits promised were also welcomed in that the initiatives that promise the benefits of new employment opportunities through foreign investment converged with macro targets of the state.

The structure of genetic research projects is, in essence, similar in both cases. In Iceland, the genomic project was established as an entrepreneurial model based on the partnership with the state but self-funding by the private sector (Gottweis & Lauss, 2012). deCODE Genetics was founded with capital provided by venture capitalist firms and funded genetic research in the country by way of further capital gains as a result of the public offering of its shares. In Newfoundland, the first genomic enterprise, Newfound Genomics, was established as a private sector joint-venture to be funded by the British biotechnology company and a local company of physicians. However, in both cases, the state has been an important actor in the proceedings of the events. In Iceland, deCODE was able to get an exclusive license, which was granted by a particular law, to establish and operate the health sector database because of state support to the project. In Newfoundland, Newfound Genomics was given loans by a state development agency to survive the economic crisis, whereas Sequence Bio, the owner of an ongoing genetic project, was able to get direct investment by the state within the context of the program to support high-growth potential start-ups.

The state plays a central role in coordinating and steering biopolitics, like its function in the nineteenth century (Gottweis, 2008, p. 24). The involvement of state actors as facilitators of these genetic projects complies with the "governmentalization of the state" notion according to which the limits and survival of the state can only be understood on the basis of general tactics of governmentality (Foucault, 1991, p. 103). Neoliberalism represents a complex and contradictory assemblage, policies, practices, and discourses rather than being an organic and consistent entity (Ylönen, 2016, p. 3). Under the neoliberal model, the governmentalized state again coordinates and steers the projects of genetic databases, which is the contemporary biopolitical project, through these complex techniques and discourses that coexist and mobilize individual conduct in line with particular political-economic ends.

Discourses about national values and uniqueness that deserve to be protected prevail in both cases. However, it has a more distinctive form in the Icelandic genome project. The private sector company succeeded in articulating its for-profit targets with national values, such as Icelandic people's enthusiasm for genealogical records. The company deployed the rhetoric of national value to convince individuals that the genetic project contributes to nation preserving their genetic heritage with technological facilities. Pálsson (2007, pp. 98-101) claims that "nationalist discourse" of "Icelandic sagas, glories of the past, the uniqueness of Icelandic heritage and interest in Nordic gene" is consistent with constructing a comprehensive database, which is an old dream to be realized with "modern bioinformatics and computer technology," even stated by Halldor Laxness during World War II, a prominent author figure of Icelandic identity. In this sense, the Icelandic model is constructed on the identity-making and cultural symbols around the Nordic culture in as well as economic benefits to the country. The participants in the project, in other words, people who do not oppose the automatic optin clause in HSD, were assured that their contribution would serve for the preservation of culture and its traditions that Icelandic people belong to and proud of. As Petersen (2005, p. 284) points out, “the notions like altruistic, gift, sharing, opportunities to help others, common interest, help those suffering from the disease have a strong resonance with an emphasis on the mutuality of interest. “ In fact, “the construction of genetic databases will be driven by demand from the commercial sector and the altruistic or scenario benefits will directly accrue to commercial enterprises, to some extent to the population, but not to sample donors” (Williams & Schroder, 2004, p. 95). The nationalist discourse was frequently deployed during the Icelandic genome project, which functioned to mask the actual beneficiary of this enterprise.

The benefit-sharing principle has been a more active element of the model developed in Newfoundland as compared to the Icelandic genome project. In some accounts, the promise of Hoffman-LaRoche for free drugs to Icelandic people within the context of the company’s collaboration with deCODE comply with the benefit-sharing principle. For instance, Knoppers (2000, p. 213) claims that contractual arrangements in Iceland, according to which Icelandic people would be given free products, tests, or drugs if they were discovered as a result of the project, is an example of the “ efforts to recognize the equitable nature of benefit sharing.” Lucas et al. (2013, pp.100- 101) point out a different perspective in that deCODE’s database would allow Roche to track the effectiveness and side effects of products easily in Iceland before post-marketing (Phase IV) trials and exemplifies an argument made by Ernir Snorrason, who left deCODE because of his concerns, in a letter to the parliamentary committee on HSD Bill supporting Roche’s drug testing intentions on Icelanders. Contrary to the blurred interpretation of the benefit-sharing principle in Iceland, Newfoundland’s provincial approval model follows and advocates a consistent scheme upon this principle. The provincial approval model was constructed upon the principle of benefit-sharing in parallel with the HUGO Ethics Committee recommendation supporting moral principles of justice and solidarity (Pullman & Latus, 2003, p. 543). The principle of solidarity stated by the HUGO is in parallel with communitarian discourses, even if its reconciliation with the focus on justice in exchange might be difficult (Andanda et al., 2013, p. 55). The *Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador Report* (2003), authored by the same academicians, emphasize the just and equitable distribution of the benefits and burdens among all parties involved in genetic research as well as protection of local communities. The distributive justice accompanied by solidarity in genetic research in the province will be approved and observed by Standing Committee on Human Genetic Research within ethics board, which will be composed of experts in genetics, medicine, pharmacology, business, law, health policy, and medical ethics according to the same report. In practice, the committee as a part of ethics boards with such comprehensive authorities was not implemented. However, the provincial ethics board has been decisive on the evaluation of the research project proposals as projected. For instance, Sequence Bio, a local biotechnology company in which the provincial government invested as well, was not able to get the approval for the genome project in the province until they appealed the decision of the ethics board in the Supreme Court. Although the Icelandic National Bioethics Committee functions similarly, the changes in the appointment of the members of the committee during the Icelandic genome project enabled politicians to intervene in the activities of this board.

The position of experts is the main point of departure between the two genomic research projects. Whereas the experts in Newfoundland have been actively involved in public debates and policy-making processes, Icelandic genomic projects excluded the experts in the early phases of the HSD Bill. The provincial government recruited medical experts to make reports and recommendations about the governance of genetic research following the increasing interest in the province in the early 2000s. Pullman and Latus (2003, p. 543) highlighted outside researchers who conduct studies in the province without informing local research and clinical communities, therefore resulting in harmful studies to the province. Their efforts to offer policy alternatives to govern research interest into the gene pool of the province strengthened the functions of the local researchers. In the Icelandic case, experts, physicians, and academicians were opposed to the HSD after the legislative bill was submitted and known by the public. Pálsson (2008, p. 42) defines the efforts of Icelandic experts against the project as biopolitics of the dispossessed, the strategies of those who feared to lose their dominance on medical practices. However, dispossession is one of the crucial notions to understand how neoliberalism functions. The reversion of common property rights (the right to a state pension, to welfare, to national healthcare) to the private domain has been one of the most egregious policies of dispossession pursued in the name of neoliberal orthodoxy (Harvey, 2003, p. 148).

The involvement of the patients and advocacy groups for patients is very limited in both cases. In the Icelandic genome project, to mention the inclusion of research participants into the debate is only possible as figures that opted out of the database because of the efforts of Mannvernd to encourage people to do so (Fortun, 2008, p. 142). However, the direct involvement of individual research subjects into the course of events was highly decisive in the future of the project. The Icelandic Supreme Court decision on the breach of personal privacy by the HSD was a consequence of the appeal of an individual. In the Newfoundland case, the names of individual research subjects were rarely stressed. The local people came only to the public’s attention in cases with a bad reputation, such as the research of Baylor University in the province. However, the high prevalence of particular diseases and the research activities of private enterprises to find remedies for these diseases were emphasized frequently, for instance, deCODE's ongoing research on twelve common diseases (Pálsson & Rabinow, 2001) and the high frequency of cardiovascular disease, diabetes, obesity and psoriasis in NL (Policy Implications of Commercial Human Genetic Research in Newfoundland and Labrador Report, 2003). In particular, the background of main figures of genomic projects working with patients in the research on locals was highlighted during the projects, such as Stefansson's effort for the multiple sclerosis patients (Rose, 2001) and Gulliver's previous research on psoriasis in the province (Pullman & Latus, 2003). In these projects, people of both places were portrayed as those who were willing to take part in the projects to be able to provide researchers with health data to mine, even though they were not able to get direct benefits for themselves, except indirect benefits through the contribution of projects into local economies which were advertised in both cases at the beginning of the projects.

5.3) Discussion

The subjectification processes, through which research subjects take part in the projects, prove that these case studies function as biopolitical projects. Under the neoliberal model that reorganizes activities and actors around the ethics of entrepreneurship, the strategies and techniques of new biopolitical projects shape themselves in compliance with the changing roles of state, private sector, experts, and individuals. If the research subjects and patients with diseases of high prevalence had been included in the debates, would these genomic research projects have been more participatory in a real sense? Would it have been possible to observe an alternative model to be shaped by the direct involvement of patients' groups and research subjects into the debates?

As Rabeharisoa and Callon (2002, p.64), this involvement can generate a third way, besides government and private sector driven research projects, which has a capacity of production and dissemination of knowledge and expertise in an alternative way. Instead of automatically opting people into databases and presupposing their participation as voluntary ones, informing them about the details of the projects is likely to create different opinions and attitudes towards the research. As Gottweis et al. (2011) claim public is not a fixed body of individuals, as phantom public, who are interested in an affair at stake and neither the time nor the interest to involve in the participatory structures of biobanks. However, people would have preferences about the goals, transparency, consent forms and, modes of operation if they are given information about them.

It is possible to multiply questions and assumptions to include other actors such as state and experts. Without the neoliberal shift, it is likely that states would respond differently to genetic research projects that challenge their sovereignty on their population by entailing private sector companies property rights on the discoveries using the gene pools of nations. How would experts have acted in the Newfoundland case if they had been excluded from the database debates at the beginning? Would Mannvernd have been established to oppose the project if the Icelandic physicians had been able to express their opinions adequately before the enactment of the HSD? Would it have been possible to propose a model to redistribute the benefits of a research project into a community if the members of that community had not accepted these projects at first for the exchange of economic benefits?

If knowledge generation through genomics had included the experiences of patients, would the costly genetic tests, which are not covered by public health systems, including prenatal screenings, have maintained their salience on predictions about genetic conditions? While these tests rely on the mining of the existing clinical data and patients taking the tests contribute to data, the costs which are not covered by public health systems are still charged directly to the patients. The case studies also show how nations, even if they are part of the Western world, are fragile against the projects aiming at the generation of value using their genetic profile considering the power of venture capital investments to convince the governments of the distressed economies to support their projects. In both cases, the mobilization of individual conduct in parallel with macroeconomic targets is observed even if there is no direct benefit for the research subjects. The promissory feature of genetics, combined with the ability of the neoliberal model to mask the discourses about the real beneficiaries, succeeds in the completion of genetic research and databases. Similar projects targeting periphery countries with very limited transparency on governance models and wider economic inequalities are likely to result in considerable damages to vulnerable populations.

Knowledge generated through genetic research is highly complex and requires expert interpretation to decide among therapy alternatives. Technical complexity is one of the greatest obstacles to translating genomics into public health practices and extend the application of personalized medicine through empowered patients. Most physicians have limited knowledge of genetics and are, therefore, not equipped to provide genetic counseling and testing (Matlof & Caplan, 2008, 6). On the patient side, there is also an urgent need for genetic testing. However, the gap between genetic knowledge and the ability to comprehend this data on the patient side is more dramatic, considering the social determinants of health. Racialized groups, ethnic minorities and adults with limited educational attainment have lower than average health literacy about genetics. This limited health literacy poses a particular challenge for effective communication with patients (Lea et al., 2011, 282). The inadequacy in the level of health literacy and numeracy through its social aspects necessitates public policies in this field beyond the mere articulation of health with the neoliberal discourse of -rational and empowered individuals.

There are contesting views regarding the governance of the genomics field to be addressed by policy-makers. Additionally, it is not a matter of preference. The hybridization of private and public and the trend towards personalized medicine, which is an integral part of genomic research, force public authorities to design policy alternatives to govern this realm. The public health and policy-making processes could benefit from genetic knowledge insofar as the alternative ways of knowledge generation are included in policy-making. For instance, the inclusion of subjunctive bodily experiences, and historically and geographically created meanings of health and illness instead of a genetic reductionist perspective generate advantages in these processes (Shostak, 2003, p. 2238). The policy-making decisions on genomics have the opportunities to find an equilibrium between the targets of economic development and public health outcomes, the empowered subjects, and the multitude of individuals amid the socially-constructed discourses.

5.4) Contributions on Literature and Future Research

This research examined the ends embedded in genomic projects, the expectations of the parties involved, and the discourses to mobilize individuals towards the anticipated ends, through a governmental analysis. Besides the analysis of micro-power relations in a Foucauldian sense, the articulations of micro with the macro-level ends in the genomics field, the neoliberal discourses of –rational individuals, and knowledge-based growth are described. The combination of these two levels provides more insightful analysis because states and international governance bodies apply the techniques and strategies, which are shaped by existing political-economic conjecture, to reach the political-economic targets. The governmentalized state shapes the discourses and is influenced by political-economic conjecture itself. The analysis of the governance of genomic research projects and genetic databases associated with them requires adequate considerations of the subjectification processes and multi-level factors, including state, private sector enterprises, as the cases in this research illustrate. In this sense, this thesis benefits from Foucault, neo-Foucauldians, who examine the micro-power relations within genomics, and also from state theory and political economy.

Future research, which will use this multi-level approach, into other sectors of biotechnology, might provide fruitful analyses about the discourses embedded in the similar genetic research projects, as well as new value creation processes. Whereas this research focuses on the cases in the Western World, the research into periphery countries, with homogenous populations, is likely to produce compelling results to discover alternative discourses and subjectification processes. The cases in this research suggest that nations and governance alternatives are fragile when they seek global investment.

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GLOSSARY

Biobanking: Biobanking describes the efforts in a legal and technological sense to construct biobanks that are the centers of biological samples and data collected through actual medical research and/or archive work (p. 63).

Bioeconomy: Bioeconomy stands for the deployment of biotechnology to produce goods and services for economic value. The industries that use biotechnological processes, such as pharmaceuticals, food, and energy sectors, are the parts of bioeconomy in general (pp. 7, 37, 44, 45).

Bioinformatics: Bioinformatics is a combination of biology and information technologies which provides data mining tools for the biological data. Within the context of the thesis, this interdisciplinary field indicates the means to crossmatch the components of the Icelandic genome project database (p. 101).

Biosociality: Biosociality describes the formation of the new group and individual identities between health and illness, such as carriers of genetic susceptibilities as a result of new techniques biotechnology (p. 8).

Biotechnology: Biotechnology or biotechnology industry represent the application of the discoveries of molecular biology to develop new techniques and technologies to create biological processes artificially or multiply them in vitro environment (pp. 1, 3, 7-9, 15, 20, 21, 23, 25, 28, 29, 31, 34- 41, 44, 48, 49, 52, 59, 61, 71, 73, 75, 77, 79, 82, 97, 100, 103, 109).

Biovalue: Biovalue refers to the yield of vitality produced by the biotechnical reformulation of living processes, as defined by Waldby (p. 19).

Gene Hunters: “ Gene Hunters” describes the endeavors to discover the population and geographies, especially homogenous populations, which are convenient to research the genetic roots of the diseases (p. 83).

Genetic Discrimination: Genetic discrimination stands for discriminative practices against people with genetic dispositions for certain diseases (p. 93).

Genome Sequencing: Genome sequencing means a detailed analysis of the DNA, whereas whole-genome sequencing is an analysis of all genomes in an organism. Within the context of this thesis, population-based genomic research, such as in the Icelandic genome project, aims at whole-genome sequencing (pp. 5, 37, 39, 77).

Genomics: Genomics as a branch of molecular biology research a genome, which is basically a complete set of DNAs (pp. 1, 2, 4, 7, 9-11, 17-23, 27, 28, 31, 35-39, 45-50, 69, 70, 72, 75, 77-79, 83, 85, 89, 95, 98, 107-109).

Genotypes: Genotypes stand for the genetically inherited traits that individuals get from their ancestors. Genotypes are decisive in the genetically inherited diseases in particular (p. 13).

Hybridization: Hybridization or hybrid policies represent the governance model through a partnership between the public and private sectors as a result of the transformation of state. Hybridization, in this sense, stands for the extension of the state function through policies conducted with private sector partnerships, as well as the growing capacity of the opinion-making of this new political-economic setting (pp. 16, 17, 19, 20, 41, 108).